FORTIFICATION OF CEREAL GRAINS WITH ESSENTIAL VITAMINS AND MINERALS

HEARING

BEFORE THE

SUBCOMMITTEE ON NATURAL RESOURCES,
AGRICULTURE RESEARCH AND ENVIRONMENT

OF THE

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CONTENTS

WITNESSES

April 29, 1982: Page

- Dr. Paul Lachance, professor of nutrition, Rutgers University 2
- Dr. Sandford A. Miller, Director, Bureau of Foods, U.S. Food and Drug Administration; accompanied by Jess H. Stribling, Jr., Deputy Chief Counsel, FDA 19
- Dr. Esther Winterfeldt, U.S. Department of Agriculture; accompanied by Catherine E. Woteki, Consumer Nutrition Center, USDA 51
- John J. Watson, president of Watson Foods Co., Inc., and current president of the American Association of Cereal Chemists 62
- Ray Sandy Sutton, vice president and general counsel, Interstate Brands Corp.: accompanied by Halleck B. Warren, vice president and director of technical services, Interstate Brands Corp 66
- Dr. James R. Kirk, Food Science and Human Department, University of Florida 71

FORTIFICATION OF CEREAL GRAINS WITH ESSENTIAL VITAMINS AND MINERALS

THURSDAY, APRIL 29, 1982

House of Representatives,
Committee on Science and Technology,
Subcommittee on Natural Resources,
Agriculture Research and Environment,
Washington, D.C.

The subcommittee met, pursuant to notice, at 1:02 p.m., in room 2325, Rayburn House Office Building, Hon. James H. Scheuer (chairman of the subcommittee) presiding.

Present: Representatives Scheuer, White, and Sensenbrenner.

Staff present: Jonah Shacknai, counsel; and Maryanne C. Bach, technical consultant.

Mr. Scheuer. This hearing of the Subcommittee on Natural Resources, Agriculture Research and Environment will come to order, and we will commence a set of oversight hearings to ascertain the current nutritional status of Americans, along with consideration of various methods of enhancing the nutritional quality of our food intake.

At this hearing, we will examine the fortification of cereal grains as one such method of improving our dietary intake, particularly for our poor and our senior citizens.

It has been established conclusively that there exists a very strong correlation between good nutrition and good health. This is consistent with our feeling that, in our health services system, there ought to be less of a predilection looking for answers through tertiary hospital care, CAT scanners and open heart surgery and sickness care in general, and more of a concentration on wellness and preventive health care.

First and foremost among all of the means for enhancing our wellness is improved nutrition. America's elderly and poor, as population groups, seem least able to ensure the nutritional adequacy of the foods they consume and are being denied healthy, nourishing diets.

Now, unfortunately, from my point of view, this administration seems intent on cutting nutritional and other preventive health programs especially designed to benefit poor and aged people. I believe we must do everything in our power to explore the availability of nutritional insurance programs.

As a matter of fact, it has been suggested by no less an authority than the National Academy of Sciences that cereal grain fortification or nutrification can be one such valuable asset in the fight against marginal nutrition deficiencies.

So we eagerly await the results of the recently completed HANES II study of nutritional intake in the United States. Obviously, only when this data is analyzed can we assess fully the nature and extent of our nutritional problems. But if recent trends continue, as indicated from various early studies, there is cause for deep concern.

So it is imperative that we have in place, ready to be implemented, cost-effective programs on the cutting edge of technology, designed to improve the nutritional content of food, especially the kinds of food that are consumed by the poor and elderly. We are here today to learn about a few such potential programs.

Now, nutrition has been of particular concern to me for a number of years. In 1977, when chairing another subcommittee of the Science and Technology Committee, I think I began the Science and Technology Committee's involvement in the whole area of nutrition, when we commenced a set of hearings on nutritional surveillance.

Since that time, several other members of the committee, particularly Congressmen George Brown of California, who serves on the Agriculture Committee, and Doug Walgren of Pennsylvania, both of whom are very valuable members of this committee, have shared my sense of concern.

The level of concern on the part of all of us has been raised by important trends in the budget with which you are all familiar.

So I am very happy at this time to be going further down the road of examining the nutritional status of our country and the potential for improving the health of Americans on a very cost-effective basis—far more cost-effective than treating the illnesses produced by malnutrition in tertiary hospitals. With hospital bed costs soaring over $300 a day, it is far cheaper to keep people well than to cure the sicknesses in a health services delivery system where hospital costs seem to be out of control and going off the chart, indeed, off the wall.

Our first witness this afternoon will be Dr. Paul Lachance, professor of nutrition science at Rutgers University.

Dr. Lachance, your full statement will be printed in the record in its entirety at the conclusion of your oral presentation, so perhaps you might want to talk to us for 8 or 10 minutes, chat with us informally, and then I am sure we will have some questions for you.

STATEMENT OF DR. PAUL LACHANCE, PROFESSOR OF NUTRITION, RUTGERS UNIVERSITY

Dr. LACHANCE. Thank you, Mr. Chairman.

It is a pleasure to be here. I am Dr. Paul Lachance, professor of food science and nutrition at Rutgers State University of New Jersey. I am a member of the American Society of Clinical Nutrition and also of the Institute of Food Technologists, so I bridge the gap and specialize in bridging the gap between applied nutrition and food technology.

I have experience in the establishment, and I am kind of proud to be in this room because I headed up the establishment of the space food program for this country, and after that, I got involved with conducting research on the fortification of tortillas in a typical village in Guatemala for 2½ years in which we had a definite impact, and then subsequently I have worked in the United States on research on food delivery systems including fortification relative to elementary school and high school children, for about 3 years. I am still involved indirectly.

I would like to speak about a few different points. First of all, I think we have to look at the profile of foods that are eaten by Americans and the fact that they have changed drastically over this century. The most dramatic change, if we are to look at it, is in the consumption of grain products. It has dropped dramatically, and I have a figure which can show that.

Not ironically, to meet the recommendations, for example, the dietary goals of the Senate Committee on Nutrition and Human Needs in 1977, it has been calculated by USDA or Mrs. Peterkin and her coworkers that cereal consumption would have to increase anywhere from 73 to 141 percent and flour consumption something like 57 to 75 percent. In other words, we would have to return to eating as much cereal grain products as we did in the late thirties, but with the advantage of the newer knowledge that we now have in nutrition.

However, Americans are perpetually worried about calories and the cost of food. That is always the thing that is out front: cost first, and then they are concerned about calories. Americans consume today fewer calories than they ever did, and we can look at the HANES I survey and show that the intake peaks at 2,800 calories for men at the age of 15 to 19 and 1,900 calories per day for women at 10 to 14 years of age, and then it just drops and drops and drops until we get to 1,700 calories for men and 1,250 calories for women by the age of 65 and later.

That is a concern, because at those levels of caloric intake, you have to be a very sophisticated individual to get all of the nutrients that are recommended by the National Academy of Sciences as far as RDA's are concerned. You would have to be a trained dietician, almost, to pull that stunt.

Now, to avoid calories and foods fallaciously considered as "fattening," which is what has happened to bread and these kinds of grain products—that has kind of been the practice, and it is a problem of education we still have to do, but we cannot wait forever. We have tried.

Now, the nutrient quality of American dietary, as judged by the most reasonable scientific information, which is the recommended dietary allowances, as far as the growth population is concerned, is skewed to poor intakes of vitamin B6, folic acid, and the minerals, magnesium and zinc, and those have been proposed to be included in bread and cereal fortification.

That data is supported by some of the HANES data and the National Food Consumption Survey data, at least for some of the nutrients. One can also compare, over time, what has happened to nutrients such as vitamins A and C, the kinds of things we used to argue about at the White House Conference.

We can see that it is getting worse instead of better. I don't want to quibble about the preciseness of the numbers. I just want to point to the fact that the numbers are getting worse in terms of meeting at least the total RDA, and that means meeting 70 percent of it—the same thing; I mean you are meeting less and less.

I believe the seriousness of this is being offset to some manner by a substantial use of vitamin and mineral food supplements, but these intakes favor those who can afford them, and we know that.

In this context, the lower-income household consumes more cereal grains. They actually are wise buyers, but there is only so much they can do. The impact of that wise buying would be substantially enhanced by a more thorough restoration and public health enrichment of cereal grain products.

I don't think we have to talk at length about the role of cereal grain products in our diets. There is no question that they are a source of key nutrients. One can give all kinds of numbers of what they are doing for us, even at the low levels we consume them at. They are a source of complex carbohydrate, something that we now have discovered is kind of important for us as far as fiber and these kinds of things.

They are a source of low-calorie density per unit volume. One can realize that meeting simply the RDA's in 1,500 calories is very tough to do, as I have pointed out before, and yet bread and rolls are a better calorie-for-nutrient bargain, for example, than Danish or doughnuts, but it is hard to turn people away from fun or foods that they enjoy.

Mr. SCHEUER. It is hard for me to turn away from testimony that I enjoy, but I am going to have to suspend for about 3 minutes to go across the hall and give another committee a quorum so they can start work.

Dr. LACHANCE. OK, fine.

Mr. SCHEUER. We will suspend for about 3 or 4 minutes.

[Recess taken.]

Mr. SCHEUER. Well, I cast my vote on an important piece of legislation across the hall. We will recommence.

OK, would you like to more or less sum up in a few minutes?

Dr. LACHANCE. Yes, I will not take long. I was speaking about the fact that cereal grains are a source of low-calorie density per unit volume and weight and also that they are a source of other physiological attributes. They have a very high satiety value. There have been a few papers published on how you can in fact lose weight if you would eat enough of it. That work needs to be confirmed, obviously, but it does show something about the quality of bread and cereal grains, which have not been promoted.

Finally, there was some work done, some calculations done by a professor at Cornell. It shows that cereal grains and cereal products such as bread and fresh vegetables are really the most energy-efficient products that we have, and they should actually be added to our diets as the first part, not later. That is where we should start if we want it to be energy efficient, which is something we ought to consider in this country.

So this leads up to the fact that we need some commonsense food product development and technology. The per capita weekly flour equivalent consumption in the United States is such that it could be bettered. It has been going down. The contribution of nutrients and health factors to the dietary is substantial. The consumer has access to food labels and U.S. RDA units. However, they do not have a feeling for caloric density which could in fact be calculated from those labels.

Further, the consumer, if he were to shift from an average current flour equivalent consumption of 2 pounds per week to the basic-four recommended 2.66 pounds per week, the advantage of the additional nutrients would also be realized at the same time if they were added.

The greatest need in the United States is for an upgraded or updated nutrient rationale and practice for cereal grains in the United States. The existing standards date from 1943 and call for the addition of only three vitamins and one mineral, and there are data to show, which I have included, that all the other minerals that we speak about and have recommended, and vitamins, are lost or deteriorated—not completely lost but deteriorated—at the same rate as those in the milling of flour.

We have un-uniform regulations in various States; some 15 states don't even require enriched flour, although it is easier for the industry to just make a common approach to all States for marketing purposes.

At the very least, there is a need for a more comprehensive restoration of white flour. I believe that the Food and Nutrition Board's recommendation is at least a place to start. It is a minimal effort, but it is worth starting there. It applies to wheat, corn, and rice, and it is technically feasible. I give a list of several scientific publications which were stimulated by that document to show that one could add it, that it would not cause problems, and everything else, and it is all there, and I don't see any point in beating it any further.

In terms of commonsense economics, it would indicate that a technological practice such as this fortification or nutrification is cost effective. It is recognized and practiced in the least-cost formulation of feeds for animals to obtain cost-effective dairy products and meat and poultry and egg products, but the paranoia seems to take precedence when the practice applies to cereal grain food products for human consumption.

In terms of commonsense nutrition, it would indicate that since nutrients are invisible and nutrition knowledge is subject to social handicaps such as functional literacy, which is fairly substantial in this country—25 percent or more are functionally illiterate in more than one area—the assurance of the intake of the RDA of nutrients by a population can be realized by a combination of this nutrification technology and education which emphasizes the consumption of the proper daily proportions of servings of plant and animal foods.

Then, lastly, a public policy commonsense would reveal that the risks of malnutrition are greater in lower-income or fixed-income populations such as the elderly. In times of "safety net" economics, this risk becomes greater, and the population as a whole shifts to greater use of flour-equivalent foods. Therefore, public policy should encourage, rather than thwart, the nutrification of cereal grain products by the private sector.

To break the stalemate, government policy should make possible the immediate adoption of the proposed National Academy fortification policy for cereal grain products. Policymakers in the United States must simply cease and desist confusing food policy and nutrition policy—they are different—as if nutrition policy were another thing that one can be partisan about. It is a question of ethical responsibility which I believe supersedes politics.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Lachance follows:]

Preprint of an article to appear i
a volume being prepared by the
American Association of Cereal
Chemists entitled "Adding Nutrien
to Foods - Where do we go from
here?"

THE ROLE OF GRAIN BASED FOOD IN SUPPLYING NUTRIENTS

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INTRODUCTION

In 1974, the Food and Nutrition Board of the Natio
Academy of Sciences published a document entitled "Prop
Fortification Policy for Cereal-Grain Products" (Food
Nutrition Board, 1974). It was recommended that all pr
ducts based on the major U.S. cereal grains, i.e., whea
corn and rice, be fortified with certain nutrients wher
technically feasible. The proposal stimulated a series
systematic studies, particularly of wheat (Davis et al.
1980) (Davis et al., 1981) and wheat flour compositon
(Kulp et al., 1980) (Keagy et al., 1980) (Lorenz et al
1980) (Ranum et al., 1980). Other studies have consid
the interaction of the addition of micronutrients upon
quality of wheat flour (Ranum et al., 1981); of bread
(Emodi et al., 1980); and, cereal-grain products (Rubi
al., 1977). Fortification technology consideration (R
1980) (Parrish et al., 1980) have also been published.

Role of Cereal Grain and Products

The role of cereal grain products in the U.S. di
been the topic of a recent review (Lachance, 1980); a
several technical books have been edited on various c
grains and products (Inglett, 1970; 1974; Luh, 1980;
Houston, 1972; Pomeranz, 1982).

To briefly synopsize all of this information is
possible, but one can highlight certain facts that un
ocably demonstrate the broad and unique role of cerea
grain food in the dietary.

On a worldwide basis, cereal-grain products constitute the most significant portion of the daily intake of calories and nutrients. In the USA, 24 percent of the average daily intake of calories and associated nutrients are attributable to cereal grain products per se. Another substantial percentage of cereal grain makes possible the quality of two other food groups; dairy products and meat, poultry and egg products. This role of cereal grains in three of the four food groups is invariably overlooked.

Cereal grain products are economical (Rehkugler, 1976) and are within the purchasing power of the majority of the population. Cereal grain products are broadly consumed, at a high frequency, by all age and income groups of the U.S. population (U.S.DHEW, 1979).

Cereal grains, uncontaminated by mycotoxins, have exceedingly low health risks attributable to endogenous naturally occurring toxicants. In other words, properly grown and handled cereal grains have a very high level of safety.

Cereal grains are associated with positive health factors: low fat, high percentage of polyunsaturated fat, and high concentration of complex carbohydrate, including nondigestible fiber. The key nutritive characceristics, including the essential amino acid profile, of the three significant cereal grains in the U.S. diet - wheat, corn and rice - are provided in Tables I and II. The nutritive value contribution of cereal grains products is reflected in the fact that Food Guides universally have advocated the consumption of a minimum of four servings of cereal grain products per day. (Ahlstrom and Rasänen, 1973)

Table I NUTRITIVE VALUE OF THREE CEREALS

	Bolted Corn Meal	Wheat Flour	White Rice
Moisture (%)	12.0	12.0	12.0
Kcal/100 gm	362	364	363
Protein (%)	9.0	10.5	6.7
Fat (%)	3.4	0.5	0.4
Carbohydrate (%)	74.5	76.1	80.4
Ash (%)	1.1	0.43	0.3
Ca (Mg/100 gm)	17	16	24
Phosphorus	223	87	94
Iron	1.8	0.8	0.8
Thiamin	0.30	0.06	0.07
Riboflavin	0.08	0.05	0.03
Niacin	1.9	0.9	1.6
Vitamin A (IU)	480	0	0

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Table II ESSENTIAL AMINO ACID CONTENT OF THE CEREAL PROTEINS

	Percentage		
	Wheat	Corn	White Rice
Arginine	14.06	9.36	8.4
Histidine	7.89	0.75	2.6
Isoleucine	0	0.8	4.5
Leucine	33.91	31.22	8.4
Lysine	5.88	6.71	3.5
Methionine	4.85	2.35	2.5
Phenylalanine	8.40	9.34	4.5
Threonine	2.0	2.90	3.9
Tryptophane	8.14	2.07	1.2
Valine	3.82	1.88	6.5

Role of Wheat and Products:

The per capita U.S. consumption of wheat cereal products is 15 times that of corn or rice. The seeds of wheat are said to be the seeds of civilization, and archeologists have found evidence of wheat as a food at Jarmo (6700 BC). It is little wonder that the word cereal comes from Ceres, the Roman goddess of agriculture and the harvest. The significant nutrients of whole wheat and wheat flour are listed in Table III. The nutrients of wheat are invariably consumed as bread and related baked goods. Around the world, bread is the principle food and provides more nutrients than any other single food source. (Pomeranz and Shellenberger, 1971). The average quantity of flour equivalent whole grain or enriched products used by U.S. households in 1977 was 2.05 pounds per week. (Hama, 1980)

Table III WHEAT, WHEAT FLOUR AND FORTIFIED FLOUR
NUTRIENT LEVEL PER 100 GM

NUTRIENT	UNIT	WHOLE WHEAT	WHEAT FLOUR*	"FNB FLOUR**
PROTEIN	G	13.8	10.9	X***
THIAMIN	MG	0.46	0.2	0.64
RIBOFLAVIN	MG	0.13	0.05	0.40
NIACIN	MG	5.5	1.35	5.3
FOLIC ACID	MG	0.04	0.02	0.07
VITAMIN B_6	MG	0.46	0.05	0.44
PANTOTHENIC ACID	MG	1.0	0.32	X
BIOTIN	MG	0.01	0.002	X
VITAMIN A	I.U.	0	0	946
VITAMIN E	MG	3.28	1.50	X
VITAMIN K	MG	0.017	0.006	X
CALCIUM	MG	35	15.8	198
IRON	MG	3.0	0.9	4.4
MAGNESIUM	MG	140	26	44
COPPER	MG	0.5	0.1	X
ZINC	MG	3.0	0.8	2.2

* 74% EXTRACTION
** PROPOSED RESTORATION/ENRICHMENT LEVEL
*** RESTORATION ALSO FEASIBLE

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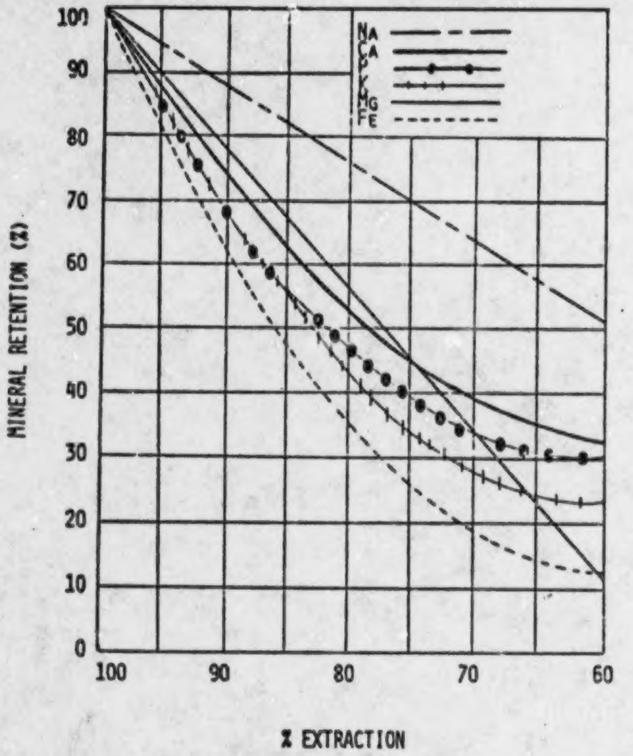

Fig. II CHANGES IN MINERAL CONTENT OF WHEAT FLOUR WITH EXTRACTION. Thomas (1968)

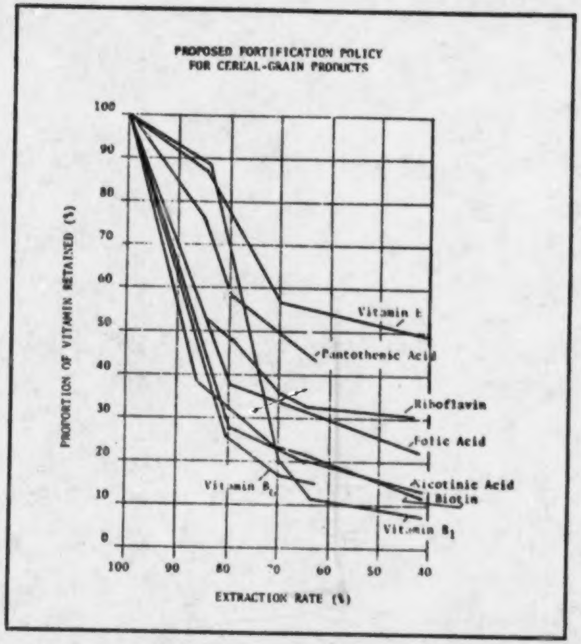

Fig. I RELATION BETWEEN RATE AND PROPORTION of total vitamins of the grain retained in flour (reproduced with permission from p.90 of Wheat in Human Nutrition; FOOD & NUTRITION BOARD 1974)

Discussion:

There is no question that the milling of grain into flour provides enhanced functional and sensory attributes, but also diminishes nutritive value attributes, (Figures I and II). Retention of the nutrient dense aleurone layer with the bran accounts for a substantial partitioning of key nutrients between the high fiber "feed" stream and the low fiber "flour" stream. The difference in nutritive value between whole wheat and wheat flour (Table III) is illustrative. What conventional nutrition wisdom overlooks is that the feed stream nutrients are realized as value-added food products in terms of dairy products and meat, poultry and egg products.

Common sense economics would indicate that a technological practice such as nutrification (restoration, public health enrichment and fortification) is cost effective. It is recognized and practiced in the least cost formulation of feeds to obtain cost effective dairy products and meat, poultry and egg products, but paranoia seems to take precedence when the practice applies to cereal grain food products for human consumption.

Common sense nutrition would indicate that since nutrients are invisible and nutrition knowledge is subject to social handicaps such as functional illiteracy, the assurance of the intake of the RDA of nutrients by a population can be realized by the combination of nutrification technology and education which emphasizes the consumption of the proper daily proportions of servings of plant and animal foods (Lachance, 1981 b) (Figure III).

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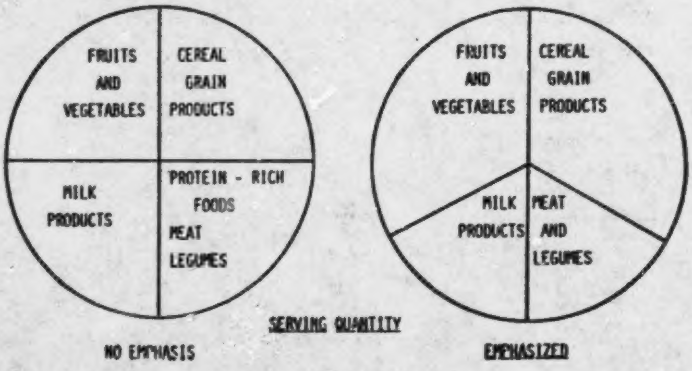

Fig. III Alternative representations of the Four Food Groups

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Common sense food product development and technology would indicate that functional and sensory characteristics notwithstanding, a responsibility exists to assure, at a minimum, that the nutritive value "image" of the product is present for the consumer to fully realize the benefits of foods (Lachance, 1972).

The per capita weekly flour equivalent consumption in the U.S. is given in Table IV. The contribution of nutrients and health factors to the dietary is substantial. The consumer has access to food labels in USRDA units. In terms of USRDA units the contribution of enriched bread and nutrified bread is self-evident (Figure IV, V). Further, if the consumer were to shift from the current average flour equivalent intake of 2.00 LB/WK to the Basic Four recommended 2.66 LB/WK, the advantage of the additional nutrients would also be realized (Table V).

Table IV

FLOUR EQUIVALENT CONSUMPTION BY ANNUAL INCOME

	LESS THAN $6,000	$6,000 TO $10,000	$10,001 TO $17,000	$17,001 TO $26,000	MORE THAN $26,001
ENRICHED OR WHOLE GRAIN (POUNDS/WEEK)	2.26	2.12	2.00	1.90	1.96

Table V

PER CAPITA FLOUR EQUIVALENT *USRDA
CONTRIBUTION OF NUTRIFIED CEREAL GRAIN

NUTRIENT/BASED ON:	2.00 LB/WK	2.66 LB/WK
(CURRENT)		
THIAMINE	50	70
RIBOFLAVIN	30	40
NIACIN	30	40
IRON (20 MG/LB)	30	40
(PROPOSED)		
VITAMIN A	25	30
VITAMIN B_6	25	35
FOLIC ACID	20	25
CALCIUM	25	30
MAGNESIUM	10	15
ZINC	15	25

*FLOUR EQUIVALENT: WEIGHT OF FLOUR, CEREALS, MEALS, PASTAS, PLUS DRY WEIGHT OF FLOUR, CEREALS, MEALS AND PASTAS IN PREPARED AND BAKERY PRODUCTS.

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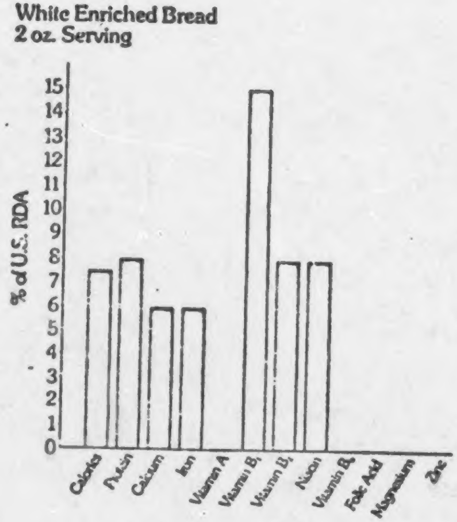

Fig. IV Usual USRDA Profile for Enriched Bread.

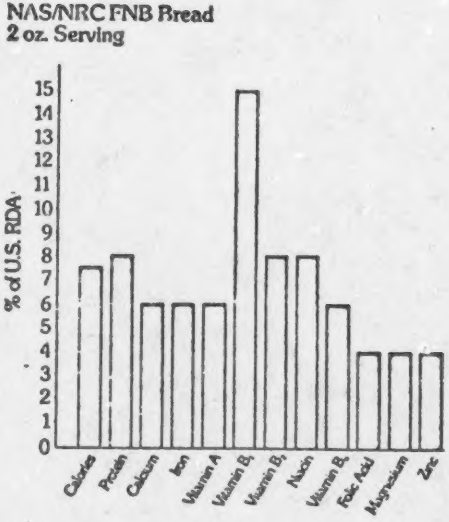

Fig. V USRDA Profile for 1974 NAS/NRC Fortified Bread.

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Public policy common sense would reveal that the risks of malnutrition are greater in lower income or fixed income populations. In times of "safety net" economics this risk becomes greater and the population as a whole shifts to greater use of flour equivalent foods, therefore, public policy should encourage rather than thwart the nutrification of cereal grain products by the private sector. To break the stalemate, executive branch should make possible the immediate adoption of the proposed NAS/NRC fortification policy for cereal-grain products by executive order. Policymakers in the U.S. must simply cease and desist confusing food policy and nutrition policy as if nutrition policy were another "thing" that one can be partisan about. It is a question of ethical responsibility which supercedes politics.

Conclusion:

The role of grain based food in supplying nutrients is most significant because of the array of nutrients involved, the range of foods having a cereal-grain component, and the long tradition of cereal-grain safety. Considering the diminishing intake of calories now practiced in the United States; poor consumer awareness of the nutritive value of grain based foods; the need to enhance the nutrient density of low cost foods for calories; and the positive role of cereal-grain products in meeting dietary goals and related guidelines, it should be evident that the implementation of the FNB proposal is long overdue.

Ahlström, A. and L. Räsänen, 1973. Review of food grouping systems in nutrition education. J. Nutr. Ed. 5(1):13-17.

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Mr. **Scheuer**. Do we have at present an adequate base of nutritional information, and an adequate data base on nutrition, to justify fortification of cereal grains?

Dr. **Lachance**. I believe we do. There are scientists, I am sure, that might quibble about that. One has to look at history to tell us the answer.

We have made interventions in terms of technology that we did not understand exactly the full science of. For example, canning was adopted or discovered by Appert in 1803 because Napoleon offered a million-dollar prize. But it was Pasteur, 50 years later, who explained why it worked.

We did not completely understand all the vitamins, nor could we measure them all, in the 1940's when we decided to enrich flour, and it became World War Food Order Number One. It was an Executive order, and it worked. We really began to see changes. Some of those changes were already occurring, but it certainly accelerated the elimination of outright fulminating cases of beriberi, ariboflavinosis, and pellagra.

Again, since they were not experiments, you cannot go out and get all the scientific community to agree, but it certainly is in that direction.

Mr. **Scheuer**. What are the implications for the poor and elderly of food grain fortification?

Dr. **Lachance**. Very substantial, because they tend to move toward those products because they are cheaper and they are filling, and so, as they do that, I sometimes tell my students, one can often find men who finally can get their pants on by 10 o'clock in the morning and amble down to Dunkin' Donuts, and it bothers me a lot that that meal does not have a nutrified grain flour to be made with, because I know that is what they are eating, and that is only one meal, and at night they may make a peanut butter sandwich or something else, and it would be awfully nice if the bread would be there.

In terms of the rest of the population, I think an important point is that fast food meals, the only common item in all fast food meals, which is a very substantial market today, is the bread item. If you look at it, it is bread. We have shown we can add these nutrients. I don't see why they aren't there. They are the nutrients that are limiting in terms of getting any kind of a decent balance in terms of the standards that we do have, that we do agree upon.

Mr. **Scheuer**. Do reductions in the Federal food programs, cutbacks in funding of these programs, make the case for fortification of grains even stronger?

Dr. **Lachance**. I believe it would because it is cost effective. You can add nutrients that are very low cost in the delivery system you have. You may have people who will stand out and say, you know, they have to have so much meat and this sort of thing, but that set, I think, is really secondary. It is a difficult argument because you can get very emotional about the ratio of these things.

Some of the things we did in our school feeding project were we fed in no-facility schools, schools that were inner city schools, where there were absolutely no kitchens whatsoever, with a nutrified kind of Danish, Danishes that were now up to standard, if you will, with a glass of milk, which provided 25 percent of the recommended dietary allowances across the board, and we got nothing but empty wrappers.

We have done it with other kinds of sandwich mixtures and things that really make sense. It can be done. We have done it. I just do not see what is holding up the works.

Mr. SCHEUER. Well, now, from the cost-benefit point of view, it makes sense. You are saying it is even more required because of the Federal cutbacks in funding for the Federal food programs.

Are there any health risks associated with that fortification program?

Dr. LACHANCE. No. In fact, there is more safety in adding nutrients to foods because you just cannot consume enough of the product to get to levels that would be considered toxic. You would have to go out of your way to do it. If you compare that, for example, to dispensing supplements, which could be a risk—we have a number of children every year who report to poison control centers because they got hold of a whole bottle of vitamin pills with iron, the iron being the problem.

Mr. SCHEUER. Yes.

Dr. LACHANCE. And so you can see the safety is kind of a self-evident kind of thing, and it is almost impossible to overfortify a food product. You run into problems technologically, either in taste or color or some other problem that would hold you back.

We have the experience, too. I think the industry has demonstrated it can do the job.

Mr. SCHEUER. Why do you think, then, that the Food and Drug Administration has delayed implementation of the fortification program?

Dr. LACHANCE. Well, I feel the scientific people in the FDA are pro the philosophy. I believe that the problem resides a lot with the way lawyers are trained, and that is that they deal with precedents of the past, and they tend to look at things that have been established for regulatory purposes, and I think that tends to hold us up rather than go forward.

It is hard to make a technological advance with that kind of philosophy. I am not demeaning the training for what it means, but it has its limitations, and I think sometimes it pervades it too much.

Mr. SCHEUER. Counsel has a question.

Mr. SHACKNAI. Dr. Lachance, several of the other witnesses, particularly from the Food and Drug Administration and the Department of Agriculture, have alluded to the danger, particularly with vitamin A, of toxicity as a result of fortification and the condition of hypervitaminosis. Is that a serious danger—elaborating on the question that Congressman Scheuer asked you about health risks?

Dr. LACHANCE. I certainly don't see it in a food system at all; I really don't. Even if you look for the actual cases of vitamin A intoxication, they are things that happened where people were put on supplements of one type or another or went berserk with a mixture of supplements and carrot juices, natural food kinds of fads.

You have to look at them, and no one died. So I think you have to be careful. I think it is something we tend to keep pointing at all the time, and I think it is kind of a tempest in a teapot, in my opinion.

It is one of my fields. I have researched vitamin A for my entire career, and I really do not feel that that kind of an argument holds a lot of water.

Mr. **Scheuer**. All right. Thank you very, very much, Dr. Lachance.

Dr. **Lachance**. Thank you.

Mr. **Scheuer**. We appreciate your testimony very much.

We will hear from the next witness, Dr. Sandy Miller, Director of the Bureau of Foods in the U.S. Food and Drug Administration.

Welcome, Dr. Miller. Your statement will be printed in full in the record at the conclusion of your oral presentation, and perhaps you will take 7 or 8 minutes to hit the high spots of your testimony, and then I am sure we will have some questions for you.

Before you start, you might want to introduce your colleague for the record.

STATEMENT OF DR. SANFORD A. MILLER, DIRECTOR, BUREAU OF FOODS, U.S. FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY: JESS H. STRIBLING, JR., DEPUTY CHIEF COUNSEL, FDA

Dr. **Miller**. Thank you, Mr. Chairman.

I have with me Mr. Jess Stribling, who is of the Office of General Counsel at the FDA.

Before I begin my statement, I want to point out a correction in the full statement. On page 15, there is an extraneous sentence. It is in the second full paragraph, and it is the sentence that begins, "It is also possible." That should come out.

Mr. **Scheuer**. Very good.

Dr. **Miller**. Thank you, Mr. Chairman, for giving us this opportunity to talk today about the issue of nutrient fortification of cereal grain products.

Let me state at the outset that we at the Food and Drug Administration believe that prudent nutrient fortification of foods is one of the most useful tools we have for the maintenance of national nutritional health.

However, as with all tools, guidelines are required to assure their most effective utilization.

It is generally agreed that the principles to be followed in fortification are: One, that the food must be an appropriate vehicle; two, that nutrient balance must be maintained; three, the nutrient must be physiologically available; and, four, that the nutrient must be stable under conditions of storage, distribution, and use.

In addition, there are two fundamental reasons why one adds nutrients to foods: First of all, to correct a recognized deficiency of one or more nutrients in the diets of a significant number of people, as determined by appropriate clinical data, when the deficit either actually or potentially affects health; and, second, to maintain the nutritional quality of the food supply at a level deemed by modern nutrition science to be appropriate to assure good nutritional health, assuming only that a reasonable variety of goods is consumed.

Now, as far the first reason is concerned, that of correcting a deficiency, fortification has been clearly demonstrated to have a dramatic effect in combating malnutrition. For example, the addition of iodine to table salt, the addition of vitamin D to milk as a vehicle to correct ricketts, and so on, I think, are well recognized examples of the success of this program.

However, certainly one of the best known examples of fortification is the enrichment of milled grain products. This practice was initiated in 1941 as a World War II order when the poor nutritional status of a major population segment became evident by the great number of young men who did not pass physicial examinations for military service.

Fortification with the B vitamins and iron was introduced to prevent beriberi, ariboflavinosis, pellagra, and iron-deficiency anemia. The success of this program can be illustrated by the fact that in 1935 there were 3,500 deaths due to pellagra and, by 1959, less than 50 deaths were attributed to this disease. Today it is a medical oddity and medical students have difficulty ever seeing these diseases in practice.

The second reason for fortification, maintenance of the nutritional quality of the food supply, has become increasingly important, in my opinion, with the changing dietary habits of the American population. It is a general trend among Americans today to consume more of their diet as processed foods rather than as fresh agricultural products. Further, there is an increasing use of nontraditional items such as vegetable protein analogues and dairy product substitutes, which also insist on some kind of concern for the nutritional quality of these products.

Certainly an example of this is the fortification of margarine when it became evident during World War II, when margarine became more widely used in place of butter, that vitamin A deficiency was possible, and as a result of this, we established a food standard in 1941 to have the vitamin A content of margarine equivalent to that of butter.

It is interesting to note that there are currently approximately 60 regulations specifically addressing nutritional quality of foods under which the FDA regulates and more than 15 regulations that are in various stages of evolution that are designed to improve the nutritional quality of foods.

Now, as suggested in your letter of invitation, I would like to now turn to the pertinent agency activity related to the implementation of the 1974 Academy's proposal for fortification policy.

The Food and Nutrition Board of the NAS/NRC conducted a review of cereal grain enrichment and in 1974 suggested levels of specific nutrients with which all major cereal grain products, primarily wheat, corn, and rice, could be fortified.

Now, while the Board also considered very limited clinical evaluations, including some biochemical studies, the nutrients recommended for inclusion in the fortification scheme were selected principally on the basis of potential dietary insufficiencies that were determined almost entirely by food consumption surveys, much of this based on 24-hour recalls.

However, for several reasons, in their evaluations the Board did not consider the technical feasibility of adding the specific nutrients at the levels recommended.

Nevertheless, in spite of the inadequacies of certain information available to the Board at that time, the FDA recognized the significance of the NAS recommendations. However, we were concerned, as was the NAS in their report, about the technical problems involved in such fortification.

Therefore, the agency contracted with the Academy Food Protection Committee to review the matter. The committee held a workshop and, in 1978, issued a report, "Technology of Fortification of Cereal-Grain Products," to address the issues.

The committee concluded that many of the recommended nutrient additions were technologically feasible but that, for some, difficulties remained. For example, calcium and magnesium needed additional evaluation before general addition to cereal grains, and so on.

However, earlier, in 1973, with full-knowledge of what the Academy was proposing as fortification policy, the FDA published an order revising its standards of identify for enriched flour, enriched self-rising flour, and enriched breads so as to be sure that our statements concerning the amount of nutrient to be added would be unambiguous.

In essence, what we proposed was to adopt or to make certain that what we had in our policy was the NAS/NRC recommended levels for thiamine, riboflavin, niacin, and iron.

While we met with no opposition concerning the specified levels for the three vitamins—and these are currently provided for in the current standard of identity—the agency was thwarted in its efforts to increase iron enrichment levels, which was perhaps the most important of the recommendations made by the NAS/NRC, by a series of objections and requests for a hearing filed in response to that 1973 order.

The principal objections raised were those of possible iron toxicity, unsubstantiated clinical benefit, and unsubstantiated efficacy in ameliorating iron deficits.

After holding public hearings, which we were compelled to do by the law, the agency issued a tentative final order in November 1977 calling for iron levels in the enriched grain products that were substantially lower than those proposed by the NAS. This decision of Commissioner Kennedy's was based primarily on the lack of adequate studies to refute the questions raised.

However, as a result of this, to provide for such evidence, the FDA undertook a major clinical nutrition research program to address the issues raised relative to the iron enrichment of bread and flour, and we anticipate that these questions will be resolved with a reasonable body of data within the next year.

Without anticipating the results of these studies that are now ongoing, it may be possible to repropose increasing levels of iron used to enrich basic staples; at least we hope so.

In January 1980, the FDA also established a clear position on food fortification by issuing a policy statement which was entitled "Nutritional Quality of Foods; Addition of Nutrients." That policy is a series of guidelines that manufacturers are urged to follow if they elect to add nutrients to a manufactured or processed food.

In developing this policy statement, FDA considered public comments on a 1974 proposal to establish general principles governing the addition of nutrients to food, plus recommendations from several scientific bodies such as the recommendations of the 1969 White House Conference on Food, Nutrition and Health, the NAS/NRC, and the American Medical Association.

The fundamental premise underlying this statement of policy is that food fortification should provide consumers with a reasonable benefit without contributing to nutritional imbalance in the diet and without misleading consumers into believing that the consumption of the fortified food, per se, will insure a complete or nutritionally sound diet. These recommendations were aimed particularly at those products that were being sold in an effort to argue that they were a complete food in and of themselves.

Now, because the development of rational regulations for the fortification of food depends on an accurate state-of-the-art scientific base, FDA contracted with NAS/NRC's Food and Nutrition Board to establish a steering committee to study the sources of data on food consumption and to suggest a system for integrating these data with that on nutritional and health status.

This report was submitted in 1981, and it makes recommendations for continuous monitoring and measuring of food consumption by individuals and population groups and for relating this information to nutrition and health status.

As you know, we along with other components of HHS and with USDA are in the process of implementing these and some other proposals for ongoing nutritional surveillance of the American public.

Certainly, from a public health point of view, the most significant study pertaining to possible changes of fortification of basic staples is the National Health and Nutrition Examination Study II, the so-called HANES II study, which covers the period of 1976 to 1980 and was conducted by the National Center for Health Statistics.

As these data are analyzed, this study will provide the finest insight to date into nutritional status of the elderly as well as other population segments and in fact will make major contributions to the understanding of nutritional status as it pertains to many of the nutrients enumerated in the original NAS/NRC proposal.

Among other issues, we will know for the first time whether public health problems actually exist relative to zinc and to folate, as has been indicated by the dietary investigations. Furthermore, significant improvement in understanding iron nutrition will become possible.

We have also contracted with the Federation of American Societies for Experimental Biology, FASEB, to review state-of-the-art considerations related to various food fortification topics. For example, they reported to us on folic acid, which report was received at the end of last year, and it concluded that if the data from studies such as HANES II warrant consideration of public health measures, then fortification programs that have demonstrated their efficacy in other countries and in the United States should be considered.

We are also concerned about studies on nutrient interactions and nutrient bioavailability, issues that have been raised about the problems of fortification.

Now, at this point, if you will permit me, I would like to make some comparison between the 1974 NAS recommendations and those of the current FDA requirement for enriched cereal grain products.

In the case of the three B vitamins, thiamine, riboflavin, and niacin, as I said earlier, there is essentially no difference between the levels recommended by NAS and those currently required by the applicable standards of identity.

Vitamin A, which was recommended by the NAS to be added to cereal grains, is not required in the FDA standards for cereal grain products because we have determined that milk and dairy products were found to be more suitable carriers for it, and therefore we provided for enrichment with vitamin A in these products.

As mentioned earlier, there may be technological problems in fortifying cereal grains to the levels recommended for calcium and magnesium and possibly several other nutrients, but I think these are capable of solution.

Some of these problems were outlined in a report from the Interindustry Committee on Cereal-Grain Fortification published in 1978. Nevertheless, in spite of the difficulties that may be present in enriching grains with calcium, calcium is provided for as an optional ingredient in our current FDA enrichment standards.

As I discussed earlier, the agency attempted to adopt the NAS recommended level for iron but was unable to sustain this higher level through administrative proceedings. I think it is important to note, Mr. Chairman, that the essential message delivered to FDA by the controversy involving iron is that changes in iron or any other nutrient fortifications should be made only on the basis of supportive clinical data because, without it, it will be difficult for the agency to maintain its position when challenged either in hearings or in the courts.

Therefore, our current requirements for iron remain at a level lower than NAS recommendations, while we are developing appropriate data.

Similarly, we are reviewing the clinical data on folic acid, and we are determining whether or not we will be able to support adding folic acid to such products.

I would like to take a second or two, or a minute or two, and talk about——

Mr. SCHEUER. Excuse me. Before you go ahead——

Dr. MILLER. Yes, sir?

Mr. SCHEUER [continuing]. Did I understand you to say a few minutes back that your fortification requirements met all the standards——

Dr. MILLER. No. What I said, sir——

Mr. SCHEUER [continuing]. Set out by the NAS?

Dr. MILLER. No, sir. What I said was for three of the vitamins, thiamine, riboflavin, and niacin, the standards were the same.

Mr. SCHEUER. OK.

Dr. MILLER. For iron, we attempted to increase the standard but were unable to support it in a hearing. Commissioner Kennedy ruled that the data that was presented did not support it at that time.

For the others, we are in the process of reviewing the possibility of doing so.

Now, I would like to return if I can to some of the general considerations relative to fortification. FDA's policy calls for fortification on the basis of demonstrated nutritional deficiency. The 1974 NAS-recommended nutrient levels are based on food consumption data. Currently, it is not possible to directly correlate food consumption data with measures of health or nutrition status except in certain extreme circumstances.

Dietary methodologies such as food diaries or 24-hour recalls reflect short-term consumption. Clinical and biochemical measurements reflect longer term aspects of health and nutrient intake. Attempts that we and others have made to correlate nutrient intake to biochemical or clinical parameters or on an individual basis, such as those measured in HANES I and in other studies, have simply not been successful.

HANES I did include clinical measurements of the nutritional status of individuals with respect to riboflavin, niacin, thiamine, vitamin D, vitamin A, vitamin C, iodine, and calcium. The percentage of individuals with positive clinical signs of deficiency was relatively very low. Unfortunately, there were no clinical data relative to nutritional status with respect to magnesium, zinc, folic acid, or B6, issues that were raised in the 1974 NAS report.

However, when the clinical data from HANES II become available, which they are now, they should shed much light on this subject.

It is important to point out that even in 1974 the Academy committee indicated that they did not have appropriate clinical data to support the results coming out of their dietary investigations. What they concluded was that only for iron was there clear evidence of deficiency among children and women of childbearing age.

Nevertheless, it was for this reason, of course, as I said before, that the FDA decided to move ahead, particularly to increase the amount of iron in the diet.

Mr. SCHEUER. And it was on that one that Commissioner Kennedy said he didn't have an adequate standard?

Dr. MILLER. Commissioner Kennedy decided, after reading the result of the record, that the evidence was not strong enough to support a benefit to the public versus a possible harm to certain individuals suffering from certain genetic disorders, and so on, and it was as a result of that that we decided that we would develop the supporting data because we believed at the time, and still do, we ought to increase the iron in enriched products.

Since the levels for some of these nutrients have been implemented by FDA regulations consistent with the NAS 1974 report and because of the controversy surrounding the iron increase, Dr. Robert O. Neshaim, chairman of the NAS panel that drafted the 1974 proposal, concluded at a recent American Association of Cereal Chemists workshop that future modifications to fortification regulations can be accomplished only when adequate data exists to satisfy the scientific community.

Dr. Nesheim cautioned that the cereal industry must move carefully to develop its nutrition case prior to actual changes in fortification levels. He urged more research including a thorough assessment of data from HANES II.

A recent letter of his to Commissioner Hayes reasserts his position, and I would like to offer that letter for the record if I may.

Mr. **Scheuer**. With no objection, it is so ordered.

Dr. **Miller**. Similarly, the recently published "General Policies for Nutrient Addition" by the American Medical Association, by the NAS/NRC Food and Nutrition Board, and the Institute of Food Technologists states that the sound fortification policies require knowledge not only of national dietary patterns but also of the nutritional status of the population.

Dr. Jean Mayer, chairman of the 1979 White House Conference on Food, Nutrition, and Health and currently president of Tufts University, has also declared that as a result of possible indiscriminate fortification of foods without good clinical and other evidence, we may find, to quote Dr. Mayer, that "we have jumped from the frying pan of feared deficiency into the fire of other real nutritional problems."

There are few regulatory impediments standing in the way of manufacturers wishing to fortify foods. Nutrients may be added to nonstandardized foods as long as their presence is declared on the label and the product bears nutritional labeling.

In addition, there is a mechanism for marketing of food that purports to be, but actually differs from, the standardized item. Temporary marketing permits for interstate shipment of such foods are provided for by regulation. A petitioner could be granted permission to test market a bread or flour with more of the same or other nutrients added, provided adequate justification and supporting data are submitted with the petition to show that it is in the public interest to do so.

When consumer acceptance and test marketing data have been obtained, such information can be used as supportive data in a subsequent petition to amend the standard of identity.

In conclusion, I think it is fair to say that the FDA strongly and enthusiastically supports prudent fortification of foods, as demonstrated by our long history of activity in this area. Within the agency there are several recently completed or continuing initiatives relative to the proper fortification of cereal grains.

However, we believe, as do most of our professional colleagues, that any fortification program must consider a food's role in our diets and its nutrient profile and address widespread dietary deficiency problems.

We also agree with our professional colleagues in nutrition that such deficiencies cannot be identified from food consumption data alone. Analysis of extant clinical and biochemical data and possible collection of additional relevant data are critical to a sound determination of the nutritional status of the population of the United States.

Data from HANES II will make a major contribution to understanding nutritional status, especially with respect to those nutrients enumerated in the 1974 NAS proposal. The agency is continuing to examine the whole issue of fortification of cereal grain products, as we have for the last 10 years. However, we strongly feel that further changes in regulations, if they are to be successfully upheld, should not be made until we have sufficient clinical and biochemical data to support these proposed regulations.

Mr. Chairman, this ends my statement. My colleague and I will be happy to answer—at least attempt to answer—any questions you have.

[The prepared statement of Dr. Miller follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT BY

SANFORD A. MILLER, Ph.D.

DIRECTOR

BUREAU OF FOODS

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON NATURAL RESOURCES,
AGRICULTURE RESEARCH AND ENVIRONMENT

COMMITTEE ON SCIENCE AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

APRIL 29, 1982

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Mr. Chairman, I wish to thank you and the members of the Subcommittee for inviting me to testify today on the role of the fortification of cereal-grain products in the alleviation of nutritional deficiencies in the United States.

Let me state at the outset that we at the Food and Drug Administration (FDA) believe that prudent nutrient fortification of foods is one of the most useful tools we have for the maintenance of national nutritional health.

The principles to be followed in fortification are: 1) the Food must be an appropriate vehicle, 2) nutrient balance must be maintained, 3) the nutrient must be physiologically available, and 4) the nutrient must be stable under conditions of storage, distribution, and use.

Reasons for Fortifying Food

There are two fundamental reasons for adding nutrients to foods consumed by the general public: 1) to correct a recognized deficiency of one or more nutrients in the diets of a significant number of people, as determined by appropriate clinical data, when the deficit either actually or potentially adversely affects health, and 2) to maintain the nutritional quality of the food supply at a level, deemed by modern nutrition science, to be appropriate to ensure good nutritional health, assuming only that a reasonable variety of foods is consumed.

Regarding the first reason, fortification has been clearly demonstrated to have a dramatic effect in combatting malnutrition. A few examples from our experience in this country will serve to illustrate this point.

The addition of iodine to table salt to prevent goiter represents the first fortification program in the United States. A movement was launched in 1922 to provide iodized salt to the public. A follow-up study in the mid-1950's showed that the incidence of goiter had dropped dramatically. Although FDA regulations have never required that salt be iodized, our regulations do require that the presence or absence of iodine be clearly labeled on salt packages.

For centuries, rickets, a bone disease of infants, was a major health problem. After the discovery of vitamin D in 1922, its use in various forms as supplements to the diet increased rapidly. As a result, rickets, at least in exaggerated degrees, has largely disappeared in the United States. This decline has been attributed primarily to the addition of vitamin D to the milk supply. FDA regulations provide for the addition of vitamin D to essentially all standardized forms of milk. Milk was considered the most appropriate vehicle for vitamin D fortification because of its high natural calcium and phosphorus content which, along with vitamin D, are all required to prevent rickets.

One of the best known examples of fortification in the United States is the enrichment of milled grain products. This practice was initiated in 1941 as a World War II order when the poor nutritional status of major population segments became evident by the great number of young men who did not pass physical examinations for military service. Fortification with the B vitamins and iron was introduced to prevent beriberi, ariboflavinosis, pellagra, and iron-deficiency anemia. The success of this program can be illustrated by the fact that in 1935 there were 3,500 deaths due to pellagra. By 1959 less than 50 deaths were attributed to this disease. Today there are essentially none.

The first FDA standard for enriched flour and farina was published in the Federal Register in May 1941. It defined levels for thiamine, riboflavin, iron, and calcium. Later (1943) niacin was included and enrichment was extended to corn meal and rice.

The second reason for fortification, maintenance of the nutritional quality of the food supply, has become increasingly important with the changing dietary habits of the American population. It is a general trend among Americans today to consume more of their diet as processed foods rather than as fresh agricultural products. Further, there is an increasing use of nontraditional items such as vegetable protein analogs and dairy product substitutes.

A historical example of fortifying a substitute food to maintain nutritional quality is margarine. Margarine became widely used during World War II when butter was in short supply. A 1941 FDA food standard required margarine to have a vitamin A content comparable to that of butter.

Currently approximately 60 regulations specifically address the nutritional quality of foods and over 15 regulations, in various stages of evolution, are designed to improve the nutritional quality of the food supply.

FDA Activities Related to NAS's Proposed Cereal-Grain Fortification Policy

I would now like to discuss pertinent Agency activities related to the 1974 publication by the National Academy of Sciences of a *Proposed Fortification Policy for Cereal-Grain Products*.

The Food and Nutrition Board of the National Academy of Sciences-National Research Council (NAS-NRC) conducted a review of cereal-grain enrichment programs and its 1974 booklet suggested levels of specific nutrients with which all major cereal-grain products, primarily wheat, corn, and rice, could be fortified. The nutrients recommended for inclusion in the fortification scheme were selected principally on the basis of potential dietary insufficiencies that were determined by food consumption surveys. The Board also considered very limited clinical evaluations, including some biochemical studies. The Board did not consider the technical feasibility of adding the specific nutrients at the levels recommended.

In spite of the inadequacies of certain information available to the Board at that time, we recognized the significance of the NAS recommendations. However, we were concerned about the technical problems involved in such fortification. Therefore, the Agency contracted with the Food Protection Committee of NAS's Food and Nutrition Board to research and report on the matter. The Committee held a workshop on the subject in May 1977 and submitted it's report, Technology of Fortification of Cereal-Grain Products, to FDA in March 1978. The Committee concluded that many of the recommended nutrient additions are technologically feasible but that some significant difficulties remain. For example, calcium and magnesium need additional evaluation before general addition to cereal-grains is feasible, zinc fortification presents some taste problems, and vitamin A stability requires further study.

On October 15, 1973, with knowledge of what NAS-NRC intended to propose in its fortification policy, FDA published an order revising the standards of identity for enriched flour, enriched self-rising flour, and enriched breads to adopt the NAS-NRC recommended levels for thiamine, riboflavin, niacin, and iron. We met with no opposition to the specified levels for the vitamins and these are provided for in the current standards of identity. However, the Agency was thwarted in its efforts to increase iron enrichment levels by a series of objections and requests for a hearing filed in response to the 1973 order. The principal objections raised were: possible iron toxicity, unsubstantiated clinical benefit, and unsubstantiated efficacy in ameliorating iron deficits.

After holding public hearings, the Agency issued a tentative final order in November 1977 calling for iron levels in the enriched grain products that were substantially lower than those proposed by NAS. This decision was based primarily on the lack of adequate studies to refute the questions raised. On February 12, 1982, we issued a final rule amending the standard of identity for enriched bread and flour.

This changed the requirements for iron enrichment from a range with maximum and minimum levels, as established in the 1977 tentative final rule, to a single-level requirement. The single level was set at the previously allowed maximum for bread with a corresponding figure for flour. FDA also undertook a major clinical nutrition research program to address the issues raised relative to the iron enrichment of bread and flour. We anticipate that the matters will be resolved with a reasonable body of data within the next year. Depending on the results, it may be possible to repropose increasing the levels of iron used to enrich basic staples.

FDA established a clear position on food fortification by issuing, on January 25, 1980, a policy statement entitled "Nutritional Quality of Foods; Addition of Nutrients." The policy is a series of guidelines that manufacturers are urged to follow if they elect to add nutrients to a manufactured or processed food. In developing the policy statement FDA considered public comments on a 1974 proposal to establish general principles governing the addition of nutrients to food plus recommendations from several scientific bodies, including the 1969 White House Conference on Food, Nutrition, and Health; the NAS-NRC; and the American Medical Association (AMA). The fundamental premise underlying this statement of policy is that food fortification should provide consumers with a reasonable benefit without contributing to nutritional imbalance in the diet and without misleading consumers into believing that the consumption of the fortified food, per se, will ensure a complete or nutritionally sound diet.

Because the development of rational regulations for the fortification of food depends on an accurate state-of-the-art scientific base, FDA contracted with NAS-NRC's Food and Nutrition Board to establish a steering committee to study the sources of data on food consumption and to suggest a system for integrating these data with that on nutritional and health status. The report submitted by the committee, "Assessing Changing Food Consumption Patterns," 1981, makes recommendations for continuous monitoring and measurement of food consumption by individuals and population groups and for relating this information to nutrition and health status.

From a public health point of view, the most significant study pertaining to possible changes of fortification of basic staples is the National Health and Nutrition Examination Survey II (NHANES-II) covering the period of 1976-1980 and conducted by the National Center for Health Statistics. As the data are analyzed, this study will provide the finest insight to date into nutritional status of the elderly as well as other population segments. It also will make major contributions to the understanding of nutritional status as it pertains to many of the nutrients enumerated in the original NAS-NRC 1974 proposal. Particularly, we will know for the first time whether public health problems exist relative to zinc deficiencies and folate deficiencies. Furthermore, a significant improvement in understanding iron nutrition will become possible.

The Food and Drug Administration, and other groups have committed significant resources to accomplish data analysis of NHANES-II as promptly as possible. An informal group known as the NHANES Users

Group has been created by FDA and the National Center for Health Statistics to further facilitate this process. The NHANES Users Group is composed of experts in nutrition from academia, industry, and government. Current estimates are that the most important analysis will be completed in approximately two years -- a task that has traditionally taken the better part of a decade to accomplish for past surveys.

In the intervening time FDA uses the Total Diet Study as a means of tracking nutrient consumption. The Total Diet Study is an annual program which involves the purchase of selected foods in grocery stores across the United States and analyses of these foods for essential minerals, heavy metals, radionuclides, industrial chemicals, and pesticides. The Total Diet Study is the only national effort for analytically determining representative diets that provides a means to monitor, on a yearly basis, the nutrient and contaminant content of the United States food supply and to observe trends in the consumption of these substances over time. The Total Diet Study allows FDA to assess the dietary exposure of selected age/sex groups to harmful contaminants and to essential minerals. Information from this study helps to identify potential public health issues that may warrant changes in agricultural or manufacturing practices or in regulatory policies concerning food additive or nutrient fortification.

FDA has also contracted with the Federation of American Societies for Experimental Biology (FASEB) to review state-of-the-art considerations related to various food fortification topics. For example, their report on folacin, received by FDA in November 1981, concludes that "if forthcoming data warrant consideration of public health measures, the fortification programs that have demonstrated their efficacy in other countries should be considered as a possible model of nutritional intervention."

Another difficult issue under consideration is the nutritional aspects of osteoporosis, especially in postmenopausal women. FASEB has completed a review for FDA of half of the puzzle, i.e., the roles of calcium, phosphorus, vitamin D, and protein. The report, received in September 1981, concludes that "there is evidence to support the prophylactic use of calcium supplementation among postmenopausal women, but its therapeutic utility remains controversial." The second half of the review process is now underway, addressing magnesium, zinc, fluoride, vitamin A, and another look at vitamin D. The ultimate role that fortification may play in at least partially ameliorating osteoporosis is certainly not clear, but it is reasonable to hypothesize that the potential for a real contribution exists.

Nutrient interactions and nutrient bioavailability are areas of continuing Agency concern. Recently FDA has focused attention on the possible interference with mineral absorption by cereal and legume protein sources, sparked particularly by the recent clinical research observations of major decreases in nonheme iron absorption in the presence of soya protein. Similarly FDA is preparing to publish regulations for vegetable protein products which will require elevated levels of zinc fortification because it is known that these products affect the bioavailability of zinc.

Comparison of NAS's Recommendations with FDA's Requirements

I believe some comparison of the 1974 NAS recommendations with the current FDA requirements for enriched cereal-grain products will be of interest.

In the case of the three B vitamins, thiamine, riboflavin, and niacin, there is essentially no difference between the levels recommended by NAS and those currently required by applicable standards of identity.

Vitamin A is not required in the FDA standards for cereal-grain products. Milk and dairy products have been found to be more suitable carriers for it and, therefore, we have provided for enrichment with vitamin A in the standards for milk products. Currently there is no clear evidence that vitamin A nutriture is a problem of public health significance in the United States.

As mentioned earlier, there are technological problems in fortifying cereal-grains to the levels recommended for calcium and magnesium. In comments to the Agency, industry sources have pointed out that such levels of calcium would cause stability, texture, and appearance problems. The Interindustry Committee on Cereal-Grain Fortification's report (1978), "Technical Feasibility of Implementing Recommendations of the National Academy of Sciences for Expanded Fortification of Cereal-Grain Products," details the following technical feasibility problems:

-- Wheat Flour - "Additional work is necessary to fully evaluate the possible adverse effects of vitamin B_6, folic acid, magnesium, and zinc on wheat flours which might be subjected to extended storage at elevated temperatures or humidities."

-- Corn - "Calcium addition to corn grits should be no more than 300 mg/lb to prevent an undesirable increase in viscosity of the cooked grits."

-- Rice - "The addition of the recommended levels of calcium and magnesium is not technically feasible using the most common process for enriching rice."

Nevertheless, because of its importance, calcium is provided for as an optional ingredient in the current FDA enrichment standards.

As I discussed earlier, the Agency attempted to adopt the NAS recommended level for iron, but was unable to sustain this higher level through administrative proceedings. The essential message delivered to FDA by the controversy is that changes in iron fortification levels should be made only on the basis of supportive clinical data. Therefore, our current requirements for iron remain at a level lower than NAS recommendations, while these data are being developed.

Relative to folic acid, dietary analyses in large-scale nutrition surveys in the United States (NHANES, NFCS) have not included calculation of folacin intakes from dietary recalls because of uncertainties and incompleteness of the data in food folate tables and because of problems concerning the microbiological assay for folate. Recent data involving small sample populations indicate that serum and red cell folate levels in the elderly may be marginally compromised. For this reason we are paying particular attention to this problem and have given it priority in our review of the NHANES II data.

Zinc was not included in large-scale dietary surveys (NHANES, NFCS) because the nutrient data base is not sufficiently complete. Blood zinc determinations are included in NHANES II. We will be studying these data to determine whether a marginal deficiency exists in any segment of the population.

General Considerations of Food Fortification

I now would like to discuss some general considerations relative to fortification. FDA's policy calls for fortification on the basis of demonstrated nutritional deficiency. The NAS recommended nutrient levels are based on food consumption data. Currently it is not possible to correlate food consumption data with measures of health or nutrition status except in extreme circumstances not encountered in the United States. Dietary methodologies such as food diaries or 24-hour recalls reflect short-term consumption. Clinical and biochemical measurements reflect longer term aspects of health and nutrient intake. Attempts to correlate nutrient intake to biochemical or clinical parameters or on individual basis as measured in NHANES I and in other studies have not been successful.

Until dietary collection methodology is improved and developed to a point where it relates to measures of health and nutrition status, it is not valid to base fortification policy on dietary data alone. For example, food consumption data from NHANES I, USDA 1965 and USDA 1977-78, as well as preliminary analysis of NHANES II, indicate low caloric intakes for age groups 55 and older. An FDA scientist is just completing a detailed study on the caloric intakes of the elderly segment of the U.S. population. This study reveals that information from national surveys may be underestimating caloric intakes. Underestimating these intakes will lead to understating the dietary status of various nutrients that are calculated from dietary information based on caloric intake.

Another example of a potentially complicating factor is the estimate that 40 to 50 percent of the population 18 years old or older now take some form of vitamin and/or mineral dietary supplement. The contribution of these supplements to nutritional status would not be reflected in levels calculated from food consumption data.

Clinical measurements to assess nutritional status also are severely narrow. NHANES I included clinical measurements of the nutritional status of individuals with respect to riboflavin, niacin, thiamine, vitamin D, vitamin A, vitamin C, iodine and calcium. The percentage of individuals with positive clinical signs of deficiency was very low. There were no clinical data relative to the nutritional status with respect to magnesium, zinc, folic acid, or vitamin B_6. When clinical data from NHANES II are available, they should shed much light on the nutritional status of these nutrients.

The text of the National Academy of Sciences' 1974 publication "Proposed Fortification Policy for Cereal-Grain Products" clearly indicates the lack of solid evidence for the recommendations for some of the nutrients included in the suggested program. The authors acknowledged that the suggested program was not based on "well-documented clinical evaluations" because such data were not available. Consequently the nutrients selected for inclusion were "based on the best information available, with a view toward adequately meeting the nutritional needs of those groups of the U.S. population that appear to be at the greatest nutritional risk."

The panel concluded that only for iron was there clear evidence of deficiency among children and women of child-bearing ages. Because dietary levels were lower than the RDA's it was inferred that thiamine, riboflavin, ascorbic acid, calcium, iron, vitamin B_6, vitamin B_{12}, and magnesium were inadequate in the American diet. No data from either survey were available for zinc or folic acid.

Since the levels for some of these nutrients have been implemented by FDA regulations consistent with the NAS 1974 report and because of the controversy surrounding the iron increase, Dr. Robert O. Nesheim, chairman of the NAS Panel that drafted the 1974 proposal, concluded at a recent American Association of Cereal Chemists workshop that future modifications to fortification regulations can be accomplished only when adequate data exist to satisfy the scientific community. Dr. Nesheim cautioned that "the cereal industry must move carefully to develop its nutrition case prior to actual changes in fortification levels." He urged more research including a thorough assessment of data from NHANES II.

The recently published "General Policies for Nutrient Addition" by AMA, NAS, and Institute of Food Technologists (IFT) states that sound fortification policies require knowledge of national dietary patterns and of the nutritional status of the population.

There are few regulatory impediments standing in the way of manufacturers wishing to fortify foods. Nutrients may be added to nonstandardized foods as long as their presence is declared on the label and the products bear nutrition labeling. It also is possible to fortify a standardized food beyond established requirements, provided the nutrient addition adheres to FDA's fortification policy guidelines and a name, distinctive from the name of the standardized food, is used.

There is another mechanism for marketing a food that purports to be but actually differs from the standardized item. Temporary marketing permits for interstate shipments of such foods are provided for by regulation. A petitioner could be granted permission to test market a "fortified bread" or "fortified flour," with more of the same and/or other nutrients added, provided adequate justification and supporting data are submitted with the petition. When consumer acceptance and test marketing data have been obtained, such information can be used as supportive data in a subsequent petition to amend the standard of identity.

Summary

In conclusion, we support prudent fortification of foods, as demonstrated by our long history of activity in this area. Within the Agency there are several recently completed or continuing initiatives relative to the proper fortification of cereal-grains. However, we believe that any fortification program must consider a food's role in our diets and its nutrient profile and address identified widespread dietary deficiency problems. We also agree with our professional colleagues in nutrition that such deficiencies cannot be identified from food consumption data alone. Analyses of extant clinical and biochemical data and possible collection of additional relevant data are critical to sound determination of the nutritional status of the population of the United States. Data from NHANES II will make major contributions to understanding nutritional status, especially with respect to those nutrients enumerated in the 1974 NAS proposal. The Agency is continuing to reexamine the whole issue of fortification of cereal-grain products. However, we strongly feel that further changes in regulations should not be made until more clinical and biochemical data are available.

Mr. Chairman, this ends my formal statment. My colleague and I will be happy to answer any questions you may have.

Mr. Scheuer. Thank you very much.

Congressman White.

Mr. White. Thank you, Mr. Chairman.

There is only one question. It is not precisely on what you have been testifying about, but it has something to do with it. We have been reading about excesses of salt being included in food, which is, I guess, a defortification of additives.

Is your agency doing anything in terms of monitoring the inclusion of excessive salt, which leads to, we understand, high blood pressure and a few things of this nature?

Dr. Miller. Well, as you know, Mr. White, we have a program, a very large program, that has been ongoing now for some time to do several things. One is to convince the industry to label products with salt, with sodium, to allow the public to know which products have large amounts of sodium and others smaller, and that has been, I think, at this point in time, very successful in this regard; second, to convince manufacturers to do the research necessary to reduce the sodium content of their products; third, to provide information to the public to indicate to them the consequences of consumption of too much sodium; and, fourth, in direct answer to your question, to increase our already ongoing program of survillance of the food supply for a variety of materials including sodium.

This is taking several forms. One is looking at labels of foods and, second, by actual analysis of food products as part of our total dietary survey.

Mr. White. Thank you very much.

Thank you, Mr. Chairman.

Mr. Scheuer. All right. There is a rollcall vote going on, and we are going to suspend for 15 minutes for us to catch that roll call vote.

Thank you very much. We will have some questions for you.

[Recess taken.]

Mr. Scheuer. OK, we will recommence.

Dr. Miller, can you tell us the scientific basis for the whole concept of the RDA's?

Mr. Miller. Well, the RDA's are a set of approximations, if you will, that are designed to give to the public some idea of what constitutes a level of nutrient intake which would assure that they, if they follow these things, would not suffer from deficiency of these nutrients.

The problem with the RDA's is one well recognized in the nutrition community. That is that there are certain peculiarities about them. A lot of it is based on ignorance and, frankly, not knowing a lot about a lot of areas. The result is, for some of the RDA's, the amounts specified are considerably in excess of the requirements of much of the population, because the RDA attempts to assure that everybody gets a sufficient amount of a nutrient, and so, looking at a distribution of nutrient requirements, the people at the bottom end of that are getting much more than the people at the top end.

Mr. Scheuer. Counsel would like to follow up on that.

Mr. Shacknai. Would you say, Dr. Miller, that there is a strong scientific basis for the current RDA's and that, when they were implemented, there existed a strong scientific basis?

Dr. **Miller.** I think there is a scientific basis for all of the RDA's, but in some cases the amount of data that we have is indirect, as based largely on animal models rather than direct human experience.

Nevertheless, they represent, I think, the best estimates we have to assure this, but recognizing that they involve large excesses of what the actual requirement may be.

Mr. **Shacknai.** So with that uncertainty and with the criticism, for example, of the National Academy's 1974 report that there may not exist an adequate clinical basis for those recommendations, an observation you made in your testimony, do you really see a dissimilarity between what you have done in the way of policy with RDA's and what you have not done because there does not, in your opinion, exist an adequate clinical basis to go ahead with a strong fortification?

Mr. **Miller.** Well, if I understand your question correctly, what we have done with the RDA is make it the basis for information on nutritional labels. This is, I think, different—we are providing information—than making a substantive change in the dietary intake of the nutrients.

The problem, you see, is that if you go back and look at that early dietary data which suggested deficiencies in a number of nutrients, and then go and look at the subsequent studies such as HANES I, and so on, which attempted to look at some of the clinical components, they don't always match up, and you begin to ask questions.

I mean, you can ask yourself the question, not only does the dietary evaluation perhaps underestimate what people are actually taking, and people may not, in a 24-hour period, tell you exactly what they are consuming because there is a thing in our society which says less is better in terms of food, anyway.

On the other hand, it may very well be that the measurements we are making in the clinical area are not sensitive enough to pick up the changes. So there are all kinds of questions being raised, and I think that is why the scientific community and ourselves have argued that in order to do this, you have got to have both the dietary indication of deficiency based on the RDA and clinical evidence that a deficiency may exist.

Mr. **Shacknai.** OK, but there is an example of agency policy that is predicated on a necessarily inexact scientific base.

Dr. **Miller.** Oh, yes. Oh, certainly. I don't think our argument about the RDA is based on inexactness; it is just that when there is clinical data available, it is better to use that, and I think that is what our colleagues in the professional community would argue, too.

Mr. **Scheuer.** When you talk about clinical data as you just did or clinical deficiencies, do you mean the presence of some kind of pathology, or do you simply mean inadequate levels of nutritional intake below the RDA?

Dr. **Miller.** Yes, I mean the presence of some kind of pathology which may be a biochemical lesion. In other words, it may not express itself in terms of any physical change at that point, but at least there is an indication metabolically, biochemically, that things aren't the way they should be, a first hint at it.

Indeed, most of the testing which was done in HANES I and II is based largely not on the obvious appearance of classical deficiencies; you don't look for beriberi, for example; you look for changes in thiamine metabolism which are indicative, that some day might reach that level. That is what we are talking about by clinical evidence of deficiency, even at that beginning level of biochemical derangement.

Mr. **Shacknai.** And you are able to assess that based on the data?

Dr. **Miller.** For many nutrients we can. For iron, we certainly can. At least we tried hard for the last 10 years to do that.

Mr. **Shacknai.** So there is something between pathology, on the one extreme, and some other nonclinical measurement like the RDA on the other extreme, and it is on the basis of that that you are making your final judgment?

Dr. **Miller.** That is exactly correct, and indeed, we are putting, I think, a significant effort of our limited research activities and at NIH as well to try to look for more of these biochemical markers that will show up before the regular clinical lesion.

The problem at the moment is that many of these are too complex to do in large scale studies, so we are trying to simplify them and look for more simple measures.

Mr. **Scheuer.** Do you think that after you complete your analysis of the HANES II data, you will be in a position to propose new fortification standards?

Dr. **Miller.** Yes, sir. I say that with some inner trepidation, having been in the agency long enough to know that there is many a slip between concept and proposal. But, nevertheless, I think that the results of the HANES II study, the results of our own ongoing investigation and other studies that are ongoing around the world will allow us to make significant changes in the current fortification policy.

Mr. **Scheuer.** Do you believe that the populations that are most at risk, namely the poor and the elderly are generally able to avail themselves of some kind of mineral or vitamin supplement, or are they really dependent on the nutritional intake of the food they consume every day?

Dr. **Miller.** That is a very difficult question to answer. I don't have any good data on that one way or the other. I know that in some cases where examination of dietary intake data would suggest the presence of a deficiency, there was no evidence of the deficiency clinically. Then we went back and looked at it. You realize that even some very poor people, and certainly a lot of older people, are taking vitamin supplements, for whatever reason they are taking them, but it is certainly not true for every poor person, in fact probably for many of them.

Mr. **Scheuer.** So you don't have any doubt that the poor and the elderly are in need of fortification to give them an adequate daily intake?

Dr. **Miller.** One of the goals of HANES II was to look at those two populations specifically. They are overrepresented in HANES II in that regard and in terms of statistical equality. I think that when that is completed we will have a much better idea what to do.

Part of the problem is going to be to try to put together a program which looks at—this is where the dietary survey becomes so important—what do these people actually eat; what do they really concentrate on in their diets; and decide whether these are the appropriate vehicles to use. It may not be, in the end, cereal grains, or it may be. I think we have got to find the best vehicle to get these things to these people. I think, at the moment, we would say it is cereal grains because it has traditionally been that.

Mr. **Scheuer.** Well, it seems to me that a decision on increasing fortification can be delayed indefinitely, raising all kinds of questions like what is the best vehicle. It seems to me that this may be a case where the perfect is the enemy of the good.

We are hoping that, promptly after your analysis of the HANES II data, you will do something. Do you think we can look forward to indefinite suspension of any action while you continue with a series of studies and more studies and further studies?

Dr. **Miller.** No, sir. I think that the history of the agency and certainly of the Bureau of Foods and of the members of the Bureau of Foods suggests against that. I think that we are all very, very cognizant of the problems of our society. I think we are all very sensitive to the issues of improving the diet, particularly of the elderly, and I assure you we will move ahead with more than all due haste in order to accomplish what we want.

Mr. **Scheuer.** I didn't say more than all due haste. What was the standard in Brown versus the Board of Education? Deliberate speed.

Dr. **Miller.** It will be more than deliberate, sir.

Mr. **Scheuer.** Take the motto of the Greeks: spuda gradeos; hasten slowly. How soon do you think you are going to complete the HANES II analysis, and how soon after that do you think you will have some fortification standards established?

Dr. **Miller.** Well, we are beginning to receive some of the data now, and what we have done, in order to facilitate the analysis of that data, is to help form a HANES II users group in which we will apportion out to various people, various agencies, private individuals, and so on, parts of the data so that, rather than having to analyze the data sequentially in one place, we will do it in parts, and also, everybody will have the same standard.

One of the troubles with HANES I, why it took so long, is that everybody came out with different sets of impressions because they were using different standards to compare it to. This time I think we will have the same standard, we will have a bunch of people doing it, and I think that in about a year we will have the first shot through, we will have a pretty good idea of what we are going at.

Now, we are going to concentrate on two issues out of this because one is the iron issue, which we are pushing very hard on, and the other is folic acid, and these two, I think, will be the first two we will go after, and then, after that, each of the others in turn.

Mr. **Scheuer.** Let me just rephrase my question. How soon are you going to complete your analysis of HANES data? How soon after that will you be promulgating fortification standards?

Dr. **Miller.** We will put together proposals probably about 1 year from now on these issues, and iron maybe before that because we have other data to work on. How soon those will issue I would not even venture to say, considering the process it has to go through in order to get out.

I would say we will propose them as quickly as we can; it will go out of the agency quickly; and then, hopefully, it will be soon published after that. I would say, in the normal process of things, probably a year after we finish—between 6 months and a year after we finish our analyses, the proposals will be out.

Mr. **Scheuer.** When are you going to finish your analyses? I am trying to get——

Dr. **Miller.** I am trying to say, in approximately 1 year we will have enough data, I think, to work on iron and folic acid as the first two.

Mr. **Scheuer.** All right. You say you will finish your analysis at least on those in the first half of 1983, right? And then proposals will go out when?

Dr. **Miller.** Probably 6 months to 9 months or so thereafter.

Mr. **Scheuer.** Well, let's say that is early in 1984.

Dr. **Miller.** Right.

Mr. **Scheuer.** Then what will the timetable be after that for actually implementing standards?

Dr. **Miller.** I will let Jess answer that because that constitutes certain requirements.

Mr. **Stribling.** Yes, Mr. Chairman. Standards of identity are amended or promulgated under that section of our statute that provides opportunities for interested parties to object, thereby triggering an administrative hearing, and I confess what is known by everybody, that our track record on hearings is not a good one. They tend to be prolonged, though we have made some advances, I think, in shortening the time.

Mr. **Scheuer.** I am having difficulty getting any specific answers out of you two gentleman. I am trying to create some kind of a time frame here.

Dr. **Miller.** Yes, sir.

Mr. **Scheuer.** You know, it seems to me that in an age where we are talking about more cost-effective government processes and doing away with regulatory overkill, there ought to be a more expeditious way of issuing standards than the kind of fuzzy, indefinite delay and bureaucratic obfuscation that we are hearing about here. This is a labyrinthian maze that we have to get through before we can serve the public and do things that we know, by any ordinary exercise of judgment, that we ought to be doing now. There is just something wrong with this process.

I started 5 years ago trying to improve the drug approval process in the Food and Drug Administration. I asked the General Accounting Office exactly 5 years ago this week to get on with the study of how we can expedite the drug constructive changes that will enhance the process radically, just quite by accident and by coincidence 18 hours before our press conference this morning where we announced the results of a year's study with 40 or 50 recommendations on how that process could be enhanced.

It can happen. The process can be improved. Maybe we ought to be thinking about improving the process in your agency.

Counsel?

Mr. **Shacknai.** In what is obviously going to be a somewhat elaborate process of proposing and ultimately promulgating standards, there is going to be a bit of uncertainty for those manufacturers that wish to fortify their products in the interim.

Now, you have indicated in your statement that there are very few regulatory impediments to manufacturers wishing to do that; yet this afternoon we are going to be hearing from a manufacturer who has evidently had an unpleasant experience in trying to do that.

Can they just distribute breads that are fortified under the normal marketing procedures? Do they have to go through such an extensive series of labeling changes that in fact there is a disincentive to the public to purchase those products?

Dr. **Miller.** Let me just make a comment that for a standardized product, at least, the company can come to us and ask—they can do one of two things. They can petition us for a change in the standard. Having made a change in standard, if we agree to propose it and the proposal is made, obviously, the petitioner cannot make an argument that it is better than anybody else's bread because it is like everybody else's bread. That is always the best way to go. If there is a sufficient reason to believe that bread ought to be fortified, then it seems to me that argument ought to be made.

The second point, it seems to me, as far as I know, and Mr. Stribling can answer this more fully, they can apply to us for a temporary marketing permit. Under that condition, and we have granted those in the past as well for a particular user——

Mr. **Scheuer.** What kind of permit?

Dr. **Miller.** A temporary marketing permit, which allows them to market a product which purports to be the standardized product but is different somehow or another, and we permit that and have permitted it in the past.

The problem comes when one attempts to make comparative statements of superiority, and there we have other regulations which define what constitutes superior and so on because, after all, one of the problems we always face is individuals who attempt to add a modicum of a nutrient to a product and then claim it is better because it has some trivial increase.

So we have set a standard which says you have to increase it by 10 percent of the RDA to call it superior. So there are those kinds of problems.

We have been very willing to cooperate with a lot of people, talk to a lot of people many times, in attempting to permit this to happen.

Mr. **Scheuer.** In permitting them to go ahead with voluntary standards?

Dr. **Miller.** Yes. In fact, we encourage them always to come in with a petition to come in and change the standard, you see, because if they have the data to do it, this makes life a lot easier for us.

Mr. **Shacknai.** But that is an expensive and cumbersome process, and there seems to be concern, at least as you have evidenced, that that data is not yet 100 percent complete enough to justify that change in the standards. At least that is what we are hearing.

So, really, the question is finding a way to ease the way for a nutrition-conscious manufacturer who wishes to fortify his bread, for example, at the NAS levels to go ahead and do so with a minimum of marketing impediments.

Dr. **Miller**. Well, it seems to me that the temporary marketing permit is the way to go for that. It becomes available——

Mr. **Shacknai**. That is a routine exercise, in your view?

Dr. **Miller**. I would say it is a reasonably common exercise. It is never routine because each application is evaluated on its own merits.

Jess, do you want to comment?

Mr. **Stribling**. I would like to add to that, Mr. Chairman, just to make sure that the whole story is before you.

The temporary marketing permit is a vehicle to enable a company to test market a product that deviates in some way from the standard of identity, from its standard of identity, and to see whether it will sell. It is designed to help the company test something before it invests a great deal in it.

There is a statutory limit on the number of months that a temporary marketing permit is open, though that can be renewed if the firm decides that, on the basis of its original 15-month period, it looks as if it has a promising product and it presents a petition to amend the standard and gets that process started while it continues to enjoy the temporary marketing permit privilege.

Mr. **Shacknai**. Just to follow up on that, there would be a tolling, then, of the 15-month period while the petition has been filed with the agency?

Mr. **Stribling**. Well, there is an original 15-month period that can be extended as the petition is filed with the agency.

Mr. Chairman, if I may clarify one other thing, I understand the Congress desire to have concrete dates. We feel the same way in wanting to know when things will be done. Some things are very much within our control in terms of how we utilize our resources and assign people. Other things in the food standard area are a little bit beyond our control in that if nobody objects to a food standard when it is proposed and issued as a final rule, it goes through in a very short period of time.

If, on the other hand, one firm objects or, in some situations, dozens of firms object, each with different axes to grind, wanting different kinds of changes made, then it requires a longer procedure, so that while we can sharpen our procedures, there are some things that are beyond us.

Mr. **Scheuer**. Why don't you give us a brief memo on that subject with the kind of delays that are inherent in the system when one or more companies do object? It may be that the system itself ought to be subject to some kind of reappraisal based on its history and the results.

Mr. **Shacknai**. Just to sum up, there should, in your view, be no impediment to a company wishing to voluntarily fortify their product with higher standards?

Mr. Stribling. Provided the requirements of the Food, Drug and Cosmetic Act and the regulations are followed, which Dr. Miller has talked about. There is a procedure for doing this, yes, sir.

Mr. Shacknai. But it is your intention, generally recognizing the value of fortification, though you are not prepared to come through with a formal standard-setting procedure, to encourage any way you can the voluntary upgrading of fortification of bread products?

Dr. Miller. That is right, within the limits of the guidelines that we set. I don't think we are interested in making a superpotent vitamin pill out of bread or any other product. I am just trying to be a little careful because, after 4 years in this job, I have discovered there are a lot of strange people out there, and I want to be sure we understand the conditions.

Mr. Scheuer. We have discovered the same thing.

Dr. Miller. I am sure you have, sir.

Mr. Scheuer. Well, I apologize for the delay and the rollcall votes. We appreciate your testimony very much.

With that, we thank you for your patience. Thank you very much for your testimony.

Dr. Miller. Thank you, sir.

Mr. Scheuer. All right, we will hear next from Dr. Esther Winterfeldt of the Department of Agriculture.

Dr. Winterfeldt, we are very happy to have you here. We are running well behind our schedule. We are going to ask you and the remaining three witnesses to stick pretty much to the 7 or 8 minutes I am talking about so that we do have time for some questions and so that we do get through the entire witness list.

Dr. Winterfeldt. Yes, sir.

Mr. Scheuer. Your entire statement will be printed in its entirety, to be redundant about it, at the conclusion of your oral presentation. So we suggest that you sort of hit the highlights, synthesize it for us. Feel free to address anything that you have heard this morning either from your side of the table or from my side.

Dr. Winterfeldt. All right.

Mr. Scheuer. Please proceed.

Dr. Winterfeldt. Thank you, Mr. Chairman.

Mr. Scheuer. Since we have all read your testimony, it would probably be expeditious if you didn't read it but just talked to us informally.

Dr. Winterfeldt. All right. I did have a greatly condensed version of what is in the full testimony.

Mr. Scheuer. If you wish to proceed that way, go ahead as you feel most comfortable.

STATEMENT OF DR. ESTHER WINTERFELDT, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY CATHERINE E. WOTEKI, CONSUMER NUTRITION CENTER, USDA

Dr. Winterfeldt. I thought that if I could address the question as to whether additional fortification of cereal grains would help to reduce the prevalence of dietary deficiencies among Americans, and, in replying to that question, present some information that is in answer to questions that immediately come to mind in attempting to pose answers to that question.

There are several of these, and I would like to simply make two or three brief statements in support of the information that we have at hand that I think provides some of those kinds of answers.

For instance, which nutrients are currently consumed at low levels is a pertinent question. Do these low levels of consumption pose significant public health problems is another question. Then, does the food supply provide sufficient amounts of these nutrients? Would cereal grain fortification to the levels recommended by NAS reduce these dietary deficiencies? Then, would cereal grain fortification to the levels recommended by NAS raise consumption of some nutrients to toxic levels? Then, is fortification technically feasible? Would the fortification nutrients be biologically available? Are cereal grains the appropriate vehicle for fortification?

I realize that some of these points already have been addressed, and I will only very briefly indicate where our stand is the same.

In regard to the first question about which nutrients are currently consumed at low levels, we can point to the 1974 report. The Food and Nutrition Board at that time identified six vitamins and four minerals that were being recommended for fortification in cereal grains, and that proposal, of course, was based on the examination of food supply data and on two national surveys that were available at that time. That was the 1965–66 Household Food Consumption Survey and the Ten-State Nutrition Survey.

Those provided evidence of potential risk of deficiencies of vitamin A, thiamine, riboflavin, niacin, vitamin B6, folacin, iron, calcium, magnesium and zinc, and these deficiencies among significant segments of the population.

Then in 1977–78, the Department conducted a new nationwide food consumption survey and an additional survey of low-income households, also. The survey in those years showed that vitamins A and B6, iron, calcium, and magnesium continued to be consumed at low levels and by significant proportions of the population.

Now, although information on the amounts of zinc and of folic acid in food is scanty, the information that we do have indicates that the consumption of these nutrients is also low.

The results of this 1977–78 survey did differ from the earlier surveys in that the intakes of thiamine, riboflavin, and niacin did appear to meet RDA, and that is partially attributable to the fact that the levels of those particular B vitamins that were proposed by the Food and Nutrition Board are already in use under the standards of enrichment that are in force.

In regard to the question as to whether these low levels of consumption may pose significant public health problems, the identification of particular nutrients as possible problems based on low or even high dietary intakes will, of course, alert specialists in food, nutrition, and public health to take action before consequences become serious. However, agreement is lacking on the level of intake that signifies a dietary problem that may in turn lead to a health problem.

The RDA's are set high enough to meet the nutritional needs of practically all healthy persons, and the RDA's, of course, are daily amounts of nutrients that are recommended for population groups by sex and age over a period of time. They are not specific requirements for individuals.

The RDA's for energy are an exception in that they are not planned to exceed requirements for most healthy individuals; they are set at what is considered to be the need. Therefore, when assessing the results of dietary surveys, dietary deficiencies as such cannot be directly equated with nutritional deficiencies. All that can be assumed is that when the amounts of nutrients consumed do fall below the RDA, some individuals would be at nutritional risk, and when the proportion with low intakes is large, the risk of deficiency in the population is thereby increased, also.

In regard to the question as to whether the food supply can provide these nutrients, the estimates of nutrient levels in the U.S. food supply do form a very unique historical series. It is valuable in assessing changes in this country's diet over the past 70 years, and those records exist.

The levels for most nutrients in the food supply are well above the RDA except for five of the nutrients identified as potential problems by both dietary and nutritional status surveys. Those are vitamin B6, folacin, magnesium, and zinc. We know these to be below the RDA in the food supply for both men and women. The levels of iron are below the RDA for women.

And then, would cereal grain fortification to the levels recommended by NAS reduce these dietary deficiencies? We felt that we needed to pose two additional questions in attempting to answer this. If individuals did consume at the midpoint of the RDA range for energy, then would average food consumption patterns in turn provide the RDA? If fortification of flour, corn meal, rice, pasta, bread and bakery products were increased to the proposed levels, what then would be the effects on average consumption patterns?

And so we looked at, first, children from 1 to 2 years. If children in this age group did consume the RDA for energy, the average food consumption would be 20 percent below the RDA for calcium, about 30 percent below for iron and zinc. Now, fortification would raise substantially the levels of these three nutrients but probably still not sufficiently so to achieve RDA.

With fortification, the food consumption pattern would provide 87 percent and 74 percent of the RDA's, respectively, in regard to those three nutrients.

In looking at the pattern that would be shown in men aged 20 to 50 years who would be supposedly consuming around 2,700 kilocalories per day, the average food consumption pattern then could be expected to be low in vitamin B6, folacin, and zinc. Again, fortification would raise the levels of these nutrients to meet or to exceed the RDA.

In women who would be consuming calories at the level of around 2,000 per day, if the consumption were at that level, then the average food consumption pattern would be below the RDA in six nutrients, and that is vitamin B6, folacin, calcium, iron, magnesium, and zinc.

Now, fortification would be expected to raise the levels of calcium, iron, and magnesium to meet or to exceed the RDA, while vitamin B6 would be at 86 percent of the RDA; folacin and zinc would be raised to about 75 percent of the RDA.

My next point I wanted to briefly make is in regard to whether cereal grain fortification to the levels recommended by the National Academy of Sciences, would it raise the consumption of some nutrients to toxic levels?

Now, we considered the possible effects of excessive intakes of vitamin A and of iron on men falling into this 20- to 50-year age group who are high consumers of grain products. If men in this age group did consume fortified flour, bread, and bakery products at the level consistent with the highest grain product consumption, then vitamin A intake would be 230 percent of the RDA and iron would be 400 percent of the RDA.

These levels, while they still remain within a range that would be considered to be safe by the Food and Nutrition Board, but there is a certain proportion of the population that is genetically predisposed to excessive absorption and storage of iron and thereby some possibility of toxicity could result. Careful attention must be given to the risk of creating such toxicities in these subpopulations when considering fortification levels.

Mr. **Scheuer**. First, could you give me an estimate of what percentage of the population we are talking about and second, what is the likelihood of reaching levels that would be toxic for them? Third, how would this toxicity, assuming they had a genetic predisposition to be sensitive to this, evidence itself and how serious would it be?

I mean, it seems to me that this is very, very speculative talk about an unknown percentage of the population suffering an indeterminate level of toxicity with undescribed results. Can you sort of quantify this for us a little bit?

Dr. **Winterfeldt**. I am not able to quantify it in exact terms. Again, I think we are going to have to depend on the clinical data coming from the HANES studies, for one, to give us some of that kind of information, if it does exist.

Mr. **Scheuer**. Well, what do you mean if it does exist? Did they cover this kind of thing in the HANES II report?

Dr. **Winterfeldt**. If there were any indication of present toxicities, it would likely be picked up through some of the clinical——

Mr. **Scheuer**. Can you find that out reasonably quickly? Could you find that out in a few days or a week?

Dr. **Winterfeldt**. I can investigate.

Mr. **Scheuer**. Would you do that?

Dr. **Winterfeldt**. OK.

Mr. **Scheuer**. And maybe you could get back to us. We are going to hold the record open for a week, anyway.

Dr. **Winterfeldt**. Yes, sir. All right, we will do that.

Mr. **Scheuer**. And what we would like to know is, what percentage of the male population presumably would consume 2½ times the normal predictable amount of bread or grain products? How large is this population group as a percentage of the total? What is the level of toxicity that they would achieve if they consumed 2½ times the predictable consumption of bread?

In practical, everyday layman-like terms, what would this level of toxicity mean? What is the threat to their health, in everyday layman terms? Is this a health-threatening condition, or is it some scientist off in his lab trying to figure out how many angels can dance on the head of a pin? What does it mean in everyday terms to consume 2½ times the amount of bread that people normally would with this concentration of fortification, in terms of understandable, comprehensible, realistic threat to health? Put it in a frame of reference that we can understand.

We are trying to engage—I want to get the attention of your colleague—in some kind of risk-benefit assessment here. If 99.9 percent of the population that we are talking about, our poor and elderly people, would have radical enhancement of their health outputs and one-tenth of 1 percent would have some kind of ephemeral threat that does not seem to be very serious but is theoretically there, then, on any risk-benefit calculus, we ought to go ahead with the enhancement program, the enrichment program.

So we want to find out, how large is the population group that might be threatened, the group that has a genetic predisposition to be sensitive, and what is the degree of toxicity that they would be subject to, and how would this, in practical terms, affect their health.

Dr. **WINTERFELDT**. Yes, sir. We will put together that information.

I will proceed to the question that has to do with whether fortification is technically feasible. Fortification of cereal grains with the six vitamins and four minerals that were recommended by the Food and Nutrition Board in 1974 is believed to be technically feasible.

A recent symposium on fortification sponsored by the American Association of Cereal Chemists concluded that apparently there are no insurmountable problems that exist in being able to do that.

Mr. **SCHEUER**. Did they take into account this genetic predisposition of a small percentage of the population to be very sensitive to moderate levels of fortification that for them might be toxic? Did they evaluate the health threats of this possible toxicity to that small client group?

Dr. **WINTERFELDT**. You are referring to whether the Food and Nutrition Board, in making the recommendations, did that?

Mr. **SCHEUER**. Yes. Did they contemplate that problem?

Dr. **WINTERFELDT**. Well, I believe that the level that was recommended is certainly considered to be well within a safe range for the population.

Mr. **SCHEUER**. For everybody or for 99.9 percent of the population? I mean, I presume that the levels that we are talking about are generally considered to be safe, but you are telling us there is a small percentage of the population that has a genetic predisposition to react to——

Dr. **WINTERFELDT**. A good bit of that evidence was assembled when the FDA had made their proposal for iron fortification along with the other levels of fortification, and much of the objections that were raised at that time centered on this issue.

Mr. **SCHEUER**. All right. Well, you are going to clarify this for us.

Dr. **WINTERFELDT**. Yes.

Mr. **SCHEUER**. Miss, we would be happy to have you join us.

Dr. **WINTERFELDT**. This is Dr. Cathy Woteki, Mr. Chairman.

Dr. **WOTEKI**. The Food and Nutrition Board, in coming up with the proposals that they made——

Mr. **SCHEUER**. Would you identify yourself for the record, please.

Dr. **Woteki**. My name is Catherine Woteki, and I will provide you with the spelling of that later.

Mr. **Scheuer**. And you are with the Department of Agriculture?

Dr. **Woteki**. Yes, in the Consumer Nutrition Center, part of the Human Nutrition Information Service.

Mr. **Scheuer**. Good.

Dr. **Woteki**. The Food and Nutrition Board, in coming up with their 1974 proposals, considered primarily dietary data, and that statement has been made before. The information that was available to them at that time was food supply data, which is the per capita availability of nutrients, and that is primarily based on marketing data.

The other source of information available to them was the 1965–66 Household Food Consumption Survey, which only looked at food consumption, and the Ten-State Nutrition Survey, which looked at some nutritional status indicators and food consumption in low-income populations in 10 States.

Now, since then, the Department of Health and Human Services conducted HANES and, as you have heard, HANES II, which did much more indepth clinical and biochemical tests than were conducted in the Ten-State Survey, and the evaluation of those data will be able to give us some good indicators of nutritional need as compared to the dietary figures that we are giving you now. The figures that we are providing in our testimony relate to the standard recommended dietary allowances.

So there is a big distinction to be drawn between a dietary deficiency such as we are talking about and an indication of biochemical or clinical signs of deficiency in the population.

Mr. **Scheuer**. I must say, to me that is a distinction without a difference, but I am sure that is due to my lack of comprehension of the situation. I don't understand the difference between a dietary deficiency and a nutritional deficiency. If what it means is that you are not getting enough diet from your food intake, isn't that both a nutritional and a dietary insufficiency?

Dr. **Woteki**. Well, if we look at an individual, take an individual, that person can show clinical signs of a nutritional deficiency, the old deficiency diseases like pellagra and beriberi that we don't see very much in our population at all. Those are very clear constellations of symptoms, and they are indicators of a very severe deficiency in the diet over a prolonged period of time.

Now, in the figures that we are giving, what we have done is to survey the population to find out what foods they are eating and then, from those surveys, we have calculated the amounts of nutrients that those people are consuming. We then compare them to a standard, the recommended dietary allowances, which as you have heard are intentionally set high to meet or exceed the nutrient requirements of the population.

So if an individual is eating food that supplies less than the recommended dietary allowance, that food may be supplying that individual's nutritional requirements, in which case there will be no clinical signs of deficiency and that diet is adequate.

But if that individual has a higher requirement, then clinical signs might be evident, or biochemical signs. So if you look at an individual, even though they are eating less than the recommended amount, it does not mean that they are not going to be meeting their requirements, because the RDA's are set high.

Mr. SCHEUER. There is a certain margin of safety built into it.

Dr. WOTEKI. That is correct.

Mr. SCHEUER. Let me ask the same question of you two ladies that I asked before. Do you feel that the nutritional inadequacies that you discuss and that have been indicated by any number of surveys among these two populations may be exacerbated by cutbacks in various nutrition programs, food programs in general?

[Pause.]

You are not rushing to the microphone.

Dr. WINTERFELDT. No, sir.

Well, I think that we would certainly say that we feel fortification can play an important role. We do continue to promote conventional foods to the fullest extent possible in order to do this.

Mr. SCHEUER. Excuse me. I am not able to hear you.

Dr. WINTERFELDT. Oh, I am sorry, Mr. Chairman.

Just to repeat that, we of course do recognize the fact that fortification can play an important role, but we do continue to promote the use of conventional foods.

Mr. SCHEUER. Is it an increasingly important role in light of the realities of this year's budget and the impact of the budget on food programs, food stamps, nutrition programs, all kinds of food programs for the poor and for the elderly?

Dr. WINTERFELDT. Is it more important to have more fortified foods available, is your point?

Mr. SCHEUER. Yes, in view of the cutbacks in many of these programs that provided heretofore more abundant food for the poor and the elderly.

Dr. WINTERFELDT. It may be. Again, we would prefer to see more of the evidence first of whether or not there really are nutritional deficiencies that accompany cutbacks in the ability of folk to buy foods, conventional foods.

Mr. SCHEUER. It is not transparently self-evident to you that when people cannot buy enough food they ipso facto suffer nutritional deficiencies?

Dr. WINTERFELDT. We do not have conclusive evidence of that.

Mr. SCHEUER. That is inadequate—there is no clincial evidence that when people don't have enough food, can't afford to buy enough food, that they suffer nutritional inadequacy?

Dr. WINTERFELDT. Well, I certainly would have to agree that it follows that——

Mr. SCHEUER. We have 5,000 years of human history that seem to offer adequate evidence of that.

Dr. WINTERFELDT. Eventually, without question, nutritional deficiencies will result.

Mr. SCHEUER. Well, I am glad we got to that answer.

Did I interrupt you while you were speaking?

Dr. WINTERFELDT. I only had a very brief further testimony.

Mr. SCHEUER. OK; go ahead.

Dr. WINTERFELDT. The point about—well, I will simply—I think we have made those couple of points.

I will give you simply a concluding statement to the effect that in reviewing the results of two recent food consumption surveys, we have found that only a very small proportion of the population consumes low levels of the already fortified B vitamins. However, vitamin A, B6, iron, calcium, magnesium do continue to be problems in that more than 30 percent of the population consumes less than 70 percent of the RDA.

Again, available evidence indicates that dietary intakes, dietary levels of zinc and folacin are below recommended levels, also.

Because cereal grains continue to be inexpensive, widely consumed, they are considered to be appropriate vehicles for fortification.

Finally, if cereal grains are fortified uniformly as proposed, there will probably not be confusion for the consuming public. The Department of Agriculture has traditionally taken a cautious approach to food fortification. We have shared the concerns of, for instance, the Food and Drug Administration about the possibility of random fortification practices. If guidelines, for instance, were not established, the food supply could be overfortified with nutrients that are simple and are inexpensive to add to food or underfortified with other nutrients such as trace minerals.

Mr. **Scheuer**. What is the danger of overfortification, as a practical matter?

Dr. **Winterfeldt**. It would relate again to possible toxicities.

Mr. **Scheuer**. Possible what?

Dr. **Winterfeldt**. Toxicities.

Mr. **Scheuer**. Well, this is a question that we asked before.

Dr. **Winterfeldt**. Yes, sir.

Mr. **Scheuer**. We are going to get some further information on that.

Dr. **Winterfeldt**. Yes, sir.

Mr. **Scheuer**. Thank you.

Dr. **Winterfeldt**. The fortification policy published by FDA in 1980, I think, has provided much-needed guidance in that complex area.

We do see fortification as a complicated issue. Nutrients are added to different foods for a variety of reasons and in a variety of ways. There are advantages to the use of fortified foods, but we do have some concern that they could be used inappropriately.

Mr. **Scheuer**. Do you mean the nutrients could be used inappropriately or the foods could be used inappropriately?

Dr. **Winterfeldt**. The fortification of specific foods.

Mr. **Scheuer**. What does the word "inappropriately" mean there?

Dr. **Winterfeldt**. The use of fortified foods inappropriately.

Mr. **Scheuer**. I don't understand how you use a food inappropriately. I mean, what do you mean? Do you mean you are eating a loaf of bread instead of two slices of bread?

Dr. **Winterfeldt**. Oh, well, the use of foods that might be very highly fortified to make up a major proportion of a person's total intake, say.

Mr. **Scheuer**. You are going to give us some examples——

Dr. **Winterfeldt**. Right, and with some possibility of imbalances among nutrients.

Mr. **Scheuer** [continuing]. So this will be comprehensible to us.

Dr. **Winterfeldt**. Yes.

Mr. **Scheuer**. All right.

Dr. **Winterfeldt**. The diets that are consumed by Americans have changed considerably since the data upon which the Board made its recommendations were collected. In addition, we do think that particular care must be given to considering the potentially adverse effects on some segments of the population.

Mr. **Scheuer**. Wait a minute. Potentially adverse effects of what?

Dr. **Winterfeldt**. The potentially adverse effects on some segments of the population. That is the point.

Mr. **Scheuer**. This is what we have discussed.

Dr. **Winterfeldt**. Yes, sir.

Mr. **Scheuer**. We are trying to get a handle on this whole problem as to—we are trying to figure out whether that is real. We talked about it before; we don't have to discuss it again. You are going to give us something on it by next week.

Our concern is that, given the enormous need for adequate vitamin and mineral intake and the likelihood of declining nutritional quality in the United States over the period of the 1980's, let us say, given all this, can we afford to wait much longer over the kind of indefinite time span that you are talking about to promulgate new and updated fortification standards?

We see an urgent need, and we see no prospect for what we consider timely action based on a pretty credible body of evidence.

Well, this is what you are going to deal with, and you are going to get something back to us within a week.

Dr. **Winterfeldt**. Yes, sir.

Mr. **Scheuer**. You know, it gives us concern that even after you finish your analysis of the HANES II data, will you be able to revise the fortification standards in a state of equanimity and serenity, or are you going to be troubled by all kinds of speculative dangers and hazards that we are not thinking about now but that may occur to somebody 6 months or a year or 2 years from now? Is this going to be an endless process? The HANES II study coming at the end of a lot of other studies and then somebody speculating about possible further hazards and then some more studies to refine and reanalyze the HANES study?

Can we ever look to the point where you will be able, with comfort, serenity, and equanimity, to say, Here's the body of evidence; it makes this kind of fortification standard credible and acceptable, and we think we ought to do it?

Dr. **Winterfeldt**. Well, I believe we would fully support what Dr. Miller from FDA said in regard to that.

Mr. **Scheuer**. He didn't say very much. He is going to give us some kind of specific ideas on timetables within another week or 10 days.

Dr. **Winterfeldt**. Right.

Mr. **Scheuer**. He didn't give us much today that would give us comfort or encouragement.

Dr. **Winterfeldt**. Yes, sir.

The HANES studies are unique studies. We have nothing comparable to them that exists now. We really do not know what the effects of present eating habits are among the populace.

Mr. **Scheuer**. Are you telling us that the eating habits of the American people have changed sufficiently since the data was collected for the HANES II studies so that, no matter what the results show, they have been more or less invalidated by the changes in eating habits that have occurred with the passage of time?

Dr. WOTEKI. We were not saying that in our testimony. We were saying that sufficient changes had occurred since 1965–66, the Household Food Consumption Survey upon which the Food and Nutrition Board made its recommendations. There has been a change since 1965–66 to 1982.

Mr. SCHEUER. Sufficient changes to what?

Dr. WOTEKI. To warrant a close scrutiny of the fortification proposals that were made in 1974.

I guess I should also point out that we at the Department of Agriculture will not be doing the analysis of the HANES data. That is a survey that was conducted by the Department of Health and Human Services, and our jurisdiction at the Department of Agriculture over fortification does not extend to cereal grain products.

Mr. SCHEUER. It does not extend to what?

Dr. WOTEKI. Cereal grain products.

Mr. SCHEUER. What does it extend to?

Dr. WOTEKI. Meat and poultry products.

Mr. SCHEUER. I see. Counsel?

Mr. SHACKNAI. Dr. Winterfeldt, Dr. Miller in his testimony, responding to a question from the Congressman, basically conceded that the RDA's, when they were established, were not based on absolute perfection in scientific data but, rather, they represented the best attempt based on the data available at that time to come up with some sort of nutritional standard.

I think that it is undeniable, certainly, that the RDA's have really been the nutritional underpinnings of much of America's diet, and it has made an enormous contribution.

The question is, in your view, can we learn from that experience, that all the data indeed not be in but you can go on reasonable evidence, given a critical need for nutritional improvement in the United States, particularly among the poor and the elderly, and go ahead with a fortification scheme, in your personal view as a professional?

Mr. SCHEUER. With the clear knowledge that all the evidence will never be in, that the last train to Buffalo will never take off?

Dr. WINTERFELDT. I feel I would have to go back to the point that was made, you see——

Mr. SCHEUER. I went to Grand Central Station yesterday, and I asked, "When is the last train to Buffalo?" The guy said to me, "You should live so long." [Laughter.]

I mean, this is sort of what we are faced with. We are waiting for all the evidence to be in.

Dr. WINTERFELDT. Well, I feel that we would have to go back to the point that we were making earlier, which is that we would much prefer to know if there really are deficiencies that are existing because of the food consumption patterns. We can identify through calculation the nutrients that we think or that we know to be in deficient intakes of persons.

Mr. SCHEUER. Yes, but by the time you finish your analysis, eating habits have changed, so you have to get a new body of data. Then you have to analyze that. By the time you finish that one, there will have been a successive change in eating habits. When do we get to the end of this thing?

Dr. WINTERFELDT. Well, all I can say is it is somewhat an inexact science.

Mr. SCHEUER. But if you recognize that, then you will say, well, maybe there have been some changes in eating habits, but this is a judgmental thing and we think there is enough of a body of evidence to show that a great deal of good will be accomplished with very little in the way of serious harm, and maybe we ought to have something comparable to a patient package insert. Maybe we ought to say on the loaf of bread that some people shouldn't eat this loaf of bread at one sitting. [Laughter.]

With a banana or a hamburger. There ought to be a termination of the research and the analysis and the speculation, and we ought to be able to act. Otherwise, why take up the thing in the first place? Why just spin a lot of bureaucratic gears? We have already been doing it for close to 20 years when we accrued the first data, right? I mean, what is the point of it all if, at some point in time, we don't say, this is the data; we have worked on it, we have studied it, we have analyzed it; we have done the best we can; we think there is a clear justification for moving ahead on this basis. Isn't that really what we want to do pretty soon?

Dr. WINTERFELDT. Well, yes, sir, but of course we need to keep collecting that kind of data because we must base, of course——

Mr. SCHEUER. Of course you want to keep collecting the data, but, you know, you can collect the data from here to eternity, and if you don't act, why collect the data; if you don't use it to justify some kind of regulatory action?

I mean, we don't collect data as an end in itself. This is a government. We've got people to think about. We collect the data to justify a certain level of regulatory activity. At some point in time you have to act.

We feel up here that we are sort of trying to punch our way out of a bag of wet Kleenex, that there is no end to the process.

Dr. WOTEKI. I think there is one point to be considered, though, Mr. Chairman, and that is that when the foods that are currently enriched and fortified, when those first began, there were very, very clear signs of deficiencies in the U.S. population, people with overt goiters, people with symptoms of thiamine, riboflavin, and niacin deficiencies.

What we are talking about now are marginal types of things. Dr. Miller used the term "biochemical lesions," levels of nutrients in the blood, for instance, that are lower than what scientists think are optimal levels, but there is some question about those optimal levels, also.

I think, also, if you look at mortality and morbidity statistics, they present a very good story. The mortality and morbidity statistics tell us that people are living longer lives and healthier lives.

Mr. SCHEUER. And part of that is due to changes in their diet——

Dr. WOTEKI. That is correct.

Mr. SCHEUER [continuing]. A sharply reduced intake of animal fat, for example, and with resultant sharply reduced levels of cholesterol and a significant reduction in heart attacks and strokes.

The Heart, Lung and Blood Institute of the National Institutes of Health has very clear evidence of that.

So the American diet has improved, with clear implications for morbidity and mortality. You are absolutely right.

Dr. **Woteki**. So what we are talking about now are additions to the food supply which may benefit some segments of the population, and there is some question about whether they may pose some potential harm to other portions of the population, and that is a very difficult question to answer with the kind of information that we have available to us.

Mr. **Scheuer**. Yes, but we have to answer it. We have to find out what some segment of the population means, and we have to find out what the seriousness of the potential harm is in order to make some judgment as to go ahead or not go ahead. It seems to me we have to bring this process to an end and come to some decisions. We have been at it for almost two decades. Isn't that true?

Dr. **Woteki**. Well, we have been fortifying for longer than that.

Mr. **Scheuer**. Yes.

Dr. **Woteki**. You do realize that we are talking now about a limited number of nutrients, and there are a large number more than the 10 that we are considering today that are known to be essential.

One of the problems that we have not discussed and which will probably come up at some point is the question of imbalances and the effects of interrelationships among different nutrients, and that is what is at, to use a trite phrase, the cutting edge of the research right now.

So the cautious approach that the Department of Agriculture and the Department of Health and Human Services are taking, I think, is a justified one.

Mr. **Scheuer**. All right. Well, we thank you very much for your patience, and we will look forward to receiving the supplementary information we have discussed in another week or 10 days. Thank you very much for your testimony.

Dr. **Winterfeldt**. Thank you, Mr. Chairman.

Mr. **Scheuer**. We will now hear from Mr. John Watson, president of Watson Foods, and Mr. Ray Sandy Sutton, general counsel of Interstate Bakeries. Is Mr. Sutton here?

Mr. **Sutton**. Mr. Chairman, I would also like to introduce Dr. Halleck B. Warren of Interstate Bakeries, who is our vice president of technical services.

Mr. **Scheuer**. Very good.

All right, why don't each of you give us a summary of your testimony in 7 or 8 minutes and then we will have questions for both of you. Of course, your prepared testimony will be printed in its entirety at the conclusion of your oral presentation.

Mr. Watson, why don't you go ahead?

STATEMENT OF JOHN J. WATSON, PRESIDENT OF WATSON FOODS CO., INC., AND CURRENT PRESIDENT OF THE AMERICAN ASSOCIATION OF CEREAL CHEMISTS

Mr. **Watson**. Thank you, Mr. Chairman, and members of the subcommittee.

I am John Watson, president of the Watson Foods Co., and I am currently president of the American Association of Cereal Chemists.

I would like to thank you for inviting me to appear before you today to offer my views on nutrition and fortification policy in the United States from the perspective of a practicing cereal chemist.

Watson Foods Co. is a formulator of vitamin-mineral premixes for flour, bread, and breakfast cereals. It was founded in the 1940's when the concept of fortification of staple foods was in its early stages of development.

I have been associated with the company since 1951. To further establish my credentials on the subject of food fortification, I have previously served as a director of the American Association of Food Chemists, which is a scientific society with concerns in all phases of food and particularly cereal grains and, very specifically, in fortification, with a nutrition division as well as a council on food fortification. I presently, as I said earlier, serve as its president at this particular point in time. I have also served on the World Health Organization Task Force on Fortification called the International Nutritional Anemia Consultative Group, concerned with iron anemia problems throughout the world.

I was particularly pleased to hear of this subcommittee's present timely inquiry into Federal food fortification policy, because of many recent studies and surveys on the nutrient intake of the population, which continue to indicate that substantial segments of the population are at risk in their nutrient intake levels when compared with the recommended consumption of these nutrients as recommended by the National Academy of Sciences' National Research Council.

Let me begin, if I may, with a brief review of the role of the Food and Nutrition Board and the National Academy of Sciences. As we have heard earlier today several times, the Food and Nutrition Board issued a report recommending the enrichment of flour with specific levels of five nutrients. Just briefly, this included both the enrichment of corn meal, grits, pasta, and rice products, to try to bring a little more perspective to all the cereal grains.

Following these reports, the Food and Drug Administration established a series of standards of identity for these enriched staple foods such as flour, bread, pasta, corn meal, and rice, which permitted the use of these nutrients as recommended by the Food and Nutrition Board for the fortification of these foods.

As you know, a standard of identity is an FDA regulation defining a particular food such as bread and specifying those ingredients which are required and those ingredients that are permitted in that food.

Many staple foods now have both a nutritional enrichment and a nonenriched standard of identity. Although the standard of identity for the most common of these staple foods, bread, did not become final until 1952, enriched bread with the five nutrients recommended in the 1940 report of the Food and Nutrition Board was marketed as early as May of 1941, so actually, within about 5 months from the time the Food and Nutrition Board had its first meeting, Mr. Chairman, enriched bread was on the marketplace, which is a very interesting contrast to what we have been seeing and discussing here today.

Mr. SCHEUER. And nobody objected?

Mr. WATSON. And nobody objected.

Mr. SCHEUER. None of those long years of appeals and delay took place?

Mr. WATSON. It took them about 7 or 8 months to put it together.

Mr. SCHEUER. Maybe there is a lesson there.

Mr. WATSON. This was done in accordance with an understanding which was reached between the Food and Nutrition Board, the FDA, and the American Bakers Association, that the formula for the enrichment of bread should be based on the recommendations, then, of the Food and Nutrition Board.

In the early seventies, the Food and Nutrition Board reconsidered the food fortification policy that it had been instrumental in creating a generation earlier, and in 1974 the Food and Nutrition Board issued a report entitled "Proposed Fortification Policy for Cereal-Grain Products."

The 1974 report of the Food and Nutrition Board was based on nutritional findings and experience since the 1940's and obviously represented an improvement in the fortification policy to meet the current needs of the U.S. population.

However, the FDA standards of identity for enriched staple foods continue to be based on the outdated nutrition findings of the 1940 Food and Nutrition Board report and do not reflect the more recent findings underlying the 1974 report.

Following publication of the proposed fortification policy for cereal grain products in 1974, the National Academy of Sciences and its Committee on Food Protection commissioned a workshop to study the feasibility of implementing the 1974 proposal. This led to the formation of a committee which was sponsored by the American Bakers Association and the American Association of Cereal Chemists, called the Inter-Industry Committee on Fortification of Cereal-Grains, with broad participation in its membership of the cereal grain industry, vitamin and mineral manufacturers, Government representatives from FDA, USDA, and AID, and academicians as well as members of several scientific and industry organizations.

Briefly, the committee studied first the natural levels of the vitamins and minerals in commercially milled wheat flour in both the United States and in Canada to determine the amount of each nutrient that would have to be added to reach the Food and Nutrition Board proposal. Each group with different areas of concern, such as bread, corn flour, biscuit and cracker manufacturers, set about to determine the effect of these proposals on their products.

Members of the faculty of Kansas State University conducted studies on many different products in support of industry efforts. Nutrient manufacturers evaluated technical feasibility in their laboratories and, with the assistance of Kansas State University, addressed the question of nutrient compatibility and stability, segregation in shipment——

Mr. SCHEUER. Mr. Watson?

Mr. WATSON. Yes?

Mr. SCHEUER. I feel very badly, but we are way behind schedule.

Mr. WATSON. All right, surely. I understand.

Mr. SCHEUER. You are reading your testimony. We simply don't have time for that.

Mr. WATSON. I apologize.

Mr. SCHEUER. I wonder if you could take a couple of minutes and sort of summarize the rest of your testimony so that we can get on to your colleague and then some questions for you.

Mr. WATSON. All right. I would be very happy to.

I think the main thrust of the testimony that I would like to get across, Mr. Chairman, is the question of technical feasibility as well as some of the marketplace problems.

Very briefly, I think the evidence, notwithstanding some of the testimony we have heard today, is very loud and clear that, for the most part, the technical feasibility of the proposals has been well established.

Mr. SCHEUER. The technical feasibility in what sense?

Mr. WATSON. Of implementing the higher levels of these nutrients or the addition of these nutrients to bread and to other cereal grain-based foods. There was some concern, for example, that flavor, off flavors might be achieved or that the product would become off colored and otherwise have less than a desirable consumer acceptance. I think this is going to be well established by Mr. Sutton, whose company has produced well over a billion loaves of bread fortified with this particular proposal of fortification, and he will be able to address that issue.

Mr. SCHEUER. I think the main item of concern to us in our wish to move ahead expeditiously with increasing fortification levels of grain is the threat to this undefined percentage of the population: how great is the threat and what is the level of toxicity that they would be subject to, with their genetic predisposition, and what does it mean in real-life terms? This is a question that we were discussing with the two witnesses that preceded you.

Mr. WATSON. Yes. Unfortunately, I am not a nutritionist, and I really cannot address that.

Mr. SCHEUER. You are saying from the point of view of production and consumer acceptance, there really are not any significant problems.

Mr. WATSON. That is correct. I would refer your committee, sir, to the iron hearings and the documentation and some of the information that was given at that time. I think Dr. Crosby suggested that the group at risk was in the area of about 100,000 of the people in population.

Mr. SCHEUER. How many?

Mr. WATSON. One hundred thousand, I believe, was the number that I recall.

Mr. SCHEUER. Out of how large a population group?

Mr. WATSON. In the whole population.

Mr. SCHEUER. Oh, out of 220 million?

Mr. WATSON. Yes, I believe that is correct, sir.

Mr. SCHEUER. Have those 100,000 people been identified, or are you just going by the percentages?

Mr. WATSON. Well, again, I think Dr. Paul Lachance, who is a nutritionist, could certainly identify this more—answer your question. Again, I am out of my field, and I apologize for that, but I was present at the iron hearings.

What I thought was particularly interesting, Mr. Chairman, about the treatment, when the hematologists were questioned about it, they were asked if in fact this group who are at risk, this group who are potentially at risk for iron overload, how are they treated? Are they put on ironrestrictive diets? The testimony clearly stated that they were not, because the problem is so great that the only way it is treated properly is actually with phlebotomy, or bleeding, in order to correct the problem.

So I found some difficulty myself in the testimony that took place on the manner in which this at-risk group is treated, because the doctors who treat them make no effort to restrict the dietary intake of iron for these people. So I would refer you to the iron hearings and those records. I think they will be very interesting.

Mr. SCHEUER. Have these people been identified in our population? Do we know of roughly 100,000 people who are at risk? Do we know who they are—name, rank, and serial number?

Mr. WATSON. I could not respond to that, sir. I really could not respond to that. I do not have that information.

Mr. SCHEUER. All right. Well, your testimony has been very helpful. We appreciate it very much.

Now let's go on to Mr. Sutton. If you can sum up your testimony in 7 or 8 minutes, and then we will have some questions.

STATEMENT OF RAY SANDY SUTTON, VICE PRESIDENT AND GENERAL COUNSEL, INTERSTATE BRANDS CORP., ACCOMPANIED BY: HALLECK B. WARREN, VICE PRESIDENT AND DIRECTOR OF TECHNICAL SERVICES, INTERSTATE BRANDS CORP.

Mr. SUTTON. Mr. Chairman, I think probably why don't we show you what we are talking about when we talk about a loaf of bread that has been enriched.

Mr. SCHEUER. Does that rye bread have caraway seeds in it?

Mr. SUTTON. No.

Mr. SCHEUER. It is not my kind of rye bread, then.

Mr. SUTTON. This is enriched white bread. This is a regular standard of identity white bread, and this is our loaf of bread that we are selling throughout the country which is to FNB standards. You may want to take those home and sample them.

Mr. SCHEUER. We are going to show compassion for the minority at this point in time. [Laughter.]

[Whereupon, the two loaves were handed to minority consultant Bach.]

Mr. SUTTON. Your Honor, about 95 percent—and I am sorry, I guess I am an attorney, so instead of "Mr. Chairman" it is "Your Honor"—95 percent of the bread that is consumed in the United States is produced by commercial bakers. We at Interstate are the third largest commercial baker in the country, and we bake coast to coast and border to border in various locations.

We have been putting this loaf of bread, which is according to the Food and Nutrition Board recommendations, on the market since 1978. We did not do it arbitrarily or without any consumer research or nutritional data, but we did it in connection with Kansas State and the American Bakers Association and came up with this what we call kind of a super bread product, which is better than the ordinary white bread and does meet the recommendations of the National Academy of Sciences' Food and Nutrition Board.

We did not run into a problem with the Food and Drug Administration until June 1981, when we received what they call, in quotes, a regulatory letter telling us that in spite of our attempts to position this loaf of bread outside the standard of identity, they still determined that it was bread and therefore we were giving the consumer more than he was entitled to and, consequently, we should stop producing this loaf of bread with additional vitamins and minerals.

We have been in contact with them in various phases of discussions since that time. We are still talking to each other. They have not seized our loaf of bread yet, and we haven't gotten to the court proceedings.

But we would like to point out that we feel that the regulatory branch of the Food and Drug Administration does not go along with what, really, the nutrition branch points out as to be good nutrition policies for the U.S. consumer. They make it very difficult for a company who sells the bread at the same price as ordinary enriched white bread to put a superior product on the market, and therefore that has been our problem with the Food and Drug Administration.

Mr. SCHEUER. They make it difficult in what sense?

Mr. SUTTON. Well, they make it difficult in the fact that we are trying to give the consumer more than what the Government standard says that he should have as far as nutrition and enrichment are concerned. We are giving him five extra vitamins and minerals, in accordance with the Food and Nutrition Board recommendations, and the Government says that because you are selling this product—it looks like bread, it tastes like bread—you are going to have to go back and quit putting those extra vitamins and minerals in your product.

Mr. SCHEUER. Is it because they are worried about the fear of this 100,000 people that we have discussed?

Mr. SUTTON. I cannot answer that.

Mr. WATSON. I am sure that is of no concern whatsoever, Mr. Chairman. No, the concern here is purely a regulatory concern.

Mr. SCHEUER. I don't understand. Everything we are talking about today is a regulatory matter. What is the concern, that you are giving them a different product?

Mr. SUTTON. We are giving them something that the standard does not say that we should be giving them under the term "bread."

Mr. SHACKNAI. Consequently, you are not allowed to call this "Mrs. Carl's Super White Bread" but instead have to call it an "enriched white loaf," when in fact, as is obvious when you taste it, it is bread in every respect except its nutritional potency.

Mr. SUTTON. That is correct.

Mr. SCHEUER. And what would you like to call it?

Mr. SUTTON. Bread. [Laughter.]

Mr. SCHEUER. And here in fact you are calling it "super white," "enriched white loaf," and you want to call it a white loaf of bread.

Mr. SUTTON. With extra vitamins and minerals. We want to tell the consumer that he is getting extra vitamins and minerals as we do on the nutritional labeled panel on the side of the white loaf.

Mr. SHACKNAI. So you are in fact being penalized by the regulatory agency involved, the FDA, for offering a product which, by any objective standard, is certainly more potent in terms of the nutrients that are being discussed.

Mr. SUTTON. That is correct.

Mr. SHACKNAI. Yet Dr. Miller has told us that the regulatory process is not an impediment to manufacturers wishing to offer a product that is fortified with additional nutrients.

Mr. SUTTON. I wish they were still here.

Mr. SHACKNAI. That is not your experience?

Mr. SUTTON. That is correct, and when you talk about temporary marketing permits, the way that they give those is within strict guidelines, and they dot your labeling and have to censor every claim that you make, and they indicated to us that we could not claim any superiority if we went for a temporary marketing permit for our white loaf.

Mr. SCHEUER. Well, why couldn't you claim what it was, which was super-duper enriched?

Mr. SUTTON. Because the Government standard does not allow you to do that.

Mr. SCHEUER. This says "enriched bread."

Mr. SUTTON. That is an ordinary loaf of enriched bread baked to Government standard, a standard-of-identity loaf of white bread.

Mr. SCHEUER. All right, and are you satisfied that this enriched bread gives you the identification you want as a bread product?

Mr. SUTTON. It is required. It is required to put "enriched bread" on that loaf of bread because it is enriched in accordance with the standard of identity of 1940.

Mr. SCHEUER. Is that satisfactory to you? Is that a kind of labeling that you feel comfortable with?

Mr. SUTTON. It is required, sir. We feel comfortable with it.

Mr. SCHEUER. All right, but you are somewhat unhappy about calling this Super White an "enriched white loaf." You feel that does not describe what it is, which is bread.

Mr. SUTTON. That is correct.

Mr. SCHEUER. As a practical matter, I think any consumer seeing this on the shelf who reached out and grabbed it would feel that he was grabbing for a loaf of bread, which he would then be informed was Super White and enriched. There would not be any doubt in his mind that he was buying a loaf of bread, would there be?

Mr. SUTTON. No.

Mr. SCHEUER. But, still and all, you would like to call it a loaf of bread.

Mr. SUTTON. That is correct.

Mr. SCHEUER. All right.

Mr. SHACKNAI. Has the FDA objected to your labeling of this product——

Mr. SUTTON. Yes.

Mr. **Scheuer**. As bread.

Mr. **Shacknai**. No, as this product is, as you have currently labeled it in this particular package?

Mr. **Sutton**. Yes.

Mr. **Shacknai**. And what is their objection?

Mr. **Sutton**. They say that we cannot put that loaf of bread on the market.

Mr. **Scheuer**. Why?

Mr. **Sutton**. Because we have extra vitamins and minerals in the product.

Mr. **Scheuer**. Do they say you can't call it bread or that you can't put it on the market?

Mr. **Sutton**. We can't put it on the market because you cannot have bread with extra vitamins and minerals.

Mr. **Scheuer**. But it isn't bread.

Mr. **Sutton**. I understand that, but they say that——

Mr. **Scheuer**. On this package, you don't use the word "bread."

Mr. **Sutton**. That is right, but they say it is still bread, even though we call it "loaf." Probably the only way we could get away is if we put "imitation bread" on the label, and I cannot imagine a manufacturer wanting to go out into the marketplace and saying, "We are baking imitation bread."

Mr. **Scheuer**. I can understand that.

Well, is anybody here from FDA? Is anybody still here from FDA?

Mr. **Braunig**. I am, but I haven't any idea what is involved with this. I am sure that there are other problems. It is just not as simple as that.

Mr. **Scheuer**. All right, we will write them a letter and ask them again to give us some additional information on this within a week or 10 days. I think it does deserve some clarification.

Is the baking industry in general—this is directed to either or both of you—supportive of this whole business of fortification that we have been discussing?

Mr. **Sutton**. I cannot speak for the industry. However, Mr. Wager, who is with the American Bakers Association, is in the rear of the room, and perhaps he could address it as an industry representative.

Mr. **Scheuer**. Mr. Wager, come on up here if you would and join us.

The question that I asked is, is the baking industry in general supportive of fortification?

Mr. **Wager**. Well, we have been exploring first the technical feasibility of the fortification of bread, as was described earlier, and we have been attempting as well to try to clarify some of these labeling problems which would remove the obstacles to widespread production and distribution of the product.

I believe, based on my conversations with other companies, that there are several others that would be willing—in fact are anxious—to move ahead with production of fortified bread if these regulatory obstacles were removed, and we would hope that your committee and that you would undertake to help us get that done so that we can move ahead and distribute what we believe is a highly nutritious product which would benefit all the American people.

Mr. **Scheuer**. Do you think that the negative experience that Mr. Sutton had—you can answer this yourself, Mr. Sutton—has been sort of a disincentive to other firms to go ahead and produce nutritionally fortified bread products?

Mr. **Wager**. No question that it has discouraged others from proceeding.

Mr. **Scheuer**. You would agree to that, Mr. Sutton?

Mr. **Sutton**. Yes, sir.

Mr. **Watson**. And that has certainly been my experience, too, Mr. Chairman.

Mr. **Scheuer**. Do you believe that the impediments to the fortification that the FDA has raised are legally defensible? Could they be challenged in a lawsuit? That is obviously not the most expeditious way to solve it, but——

Mr. **Sutton**. They could be challenged in a lawsuit, but it would be expensive and time-consuming litigation.

Mr. **Scheuer**. Well, it is our business to see that what is rational and supportive of the health of the American people is done through administrative action or legislative action. We certainly would look upon a lawsuit as a very poor way of implementing the public health. We are not primarily interested in corporate profits; we are interested in the health of the American people.

Mr. **Wager**. Mr. Chairman, what you have is really a catch 22 kind of policy. They have this document out there which supposedly permits and encourages fortification, and then at the same time they propose all of these—they have these regulatory obstacles which say, Well, you can't call it bread and you can't tell them what's in it, and all of these other minor hurdles that you have to get over before you can get the product out there.

If we could get that catch 22 straightened out, it would be very helpful.

Mr. **Scheuer**. It is a mare's nest, isn't it?

Mr. **Wager**. It sure is.

Mr. **Scheuer**. All right. We will try to draft a request for further information on this from the FDA. I am really sorry that we didn't have this discussion while they were present.

Excuse me, to the gentleman from FDA. Who would be the person for us to address on this?

Mr. **Braunig**. I would write directly to the Commissioner.

Mr. **Scheuer**. All right, very good. We will do that.

Any further questions?

Mr. **Shacknai**. This white bread is good. [Laughter.]

Mr. **Scheuer**. You have a vote of confidence.

Thank you very, very much. We appreciate your testimony.

Mr. **Sutton**. We will leave you two extra loaves here, too.

Mr. **Scheuer**. Oh, swell.

Ms. **Bach**. Mr. Chairman, I will give that to the majority.

Mr. **Scheuer**. We are now down to the last witness, Dr. James Kirk, professor of nutrition, University of Florida.

We would like to suggest to you to take the same 7 or 8 minutes that the other witnesses have used. We would suggest that you sum up rather than read your testimony so that we have time for a couple of questions.

Dr. **Kirk**. Will do.

STATEMENT OF DR. JAMES R. KIRK, FOOD SCIENCE AND HUMAN DEPARTMENT, UNIVERSITY OF FLORIDA

Dr. Kirk. Thank you very much, Mr. Chairman, for the opportunity to testify this afternoon and offer my comments.

I think, to bring out a few points that maybe have not been discussed in full detail, although fortification and enrichment of foods has been effective in removing the clinical manifestations of malnutrition from the general U.S. population, such programs are not the sole answer to malnutrition or marginal nutrient intakes in selected population subgroups such as the elderly.

Of course, the reason for this is that not all people within a population subgroup eat fortified or enriched foods in sufficient quantity or with sufficient frequency to eliminate nutrient deficiencies, and enriched foods do not contain all nutrients for which RDA's are known, and fortified foods only contain micronutrients for which an RDA has been established. This, then, may limit fortification or enrichment to approximately 19 nutrients, while current scientific data indicate that there are probably more like 50 or 53 nutrients required by humans. Of course, this expands each year as nutrition research sort of at the cutting edge expands the number of requirements.

Thus, fortification of foods as a means of alleviating nutrient deficiencies could lead an individual into a false sense of security by allowing the individual to believe that his or her nutrient requirements have been met by consuming fortified or enriched foods and effecting a general decline in good eating habits in this section of our population subgroup.

I am not opposed to the revision of nutrient fortification policies—in fact look forward to it—but I think certain criteria must be used in formulating such a policy. First, the fortification or enrichment policy must be instituted on the basis of the confirmed nutrient need or nutrient deficiency in a significant segment of the population, and the data to support this nutrient deficiency, of course, must be more than just household consumption data or food disappearance data which have, of course, limitations with respect to sampling, analytical and reporting errors.

It is important that we have available and use sufficient scientific data including clinical and physiological nutrient status data such as that provided by the HANES I survey and soon the HANES II survey, which document these needs.

Now, even the data from the HANES II survey may not clearly show nutrient problems or nutrient deficiencies such as low dietary intakes and physiological levels of zinc, folate, and B6. These problems may require additional data from nutritional assessment studies to adequately quantify these problems. Of course, this brings out, and we should emphasize, another problem, and that is that the data from HANES II survey and other nutritional studies, of course, are so massive that a great number of manhours will be required before it can be reduced to a useful document that will express the nutritional status of various population subgroups within the United States.

If the data from these nutritional surveys justify the revision of current nutrient fortification policies, then it should relate to the general population and not just to specific population subgroups. Fortification of foods for specific population subgroups could lead, of course, to a higher food cost for those population subgroups, and then, of course, as has been discussed here previously, possible toxicity of certain nutrients, not only for that particular population subgroup but possibly for population subgroups that those foods were not necessarily designed for, where they might be brought into the diet without the proper education and therefore chosen for these foods to be used in a regular pattern.

Mr. SCHEUER. Do you have any idea, realistically speaking, of what this toxicity idea would comprehend?

Dr. KIRK. Well, of course, if you are talking with vitamin D, you are talking about possible calcification of soft tissues, which I do not think we are necessarily interested in. If you are talking about vitamin A, you are talking about liver impairment and also other problems. If you are talking about the zinc and iron levels, the iron, specifically, is one of the ones that was talked about earlier, and that seems to be a problem in terms of blood and in terms of the red blood cells.

In terms of the actual clinical applications of how you solve those, I am not sufficiently versed in clinical nutrition to be able to answer that particular question.

Mr. SCHEUER. Well, I mean, I remember when we were talking about saccharin. We were talking about mice that got 50 cans of soft drinks a day or 1,000 packages of Sweet 'n Low a day. You are talking about a possible kidney problem, possible blood problem, possible soft tissue problem in the amounts that this bread is likely to be eaten. What is the order of magnitude of the risk to kidney patients, to blood, kidneys, to soft tissues? How large a percentage of the population is involved? Is this the one two-hundredths of 1 percent that we are talking about, 100,000 people out of 220 million?

Dr. KIRK. A very difficult question, and it is a very good question. The first part is that I don't think it is possible to answer those data or that question on the data that we have, and I think maybe the HANES II survey data will help answer some of those.

However, I think it is not just fortification of that bread. If you are talking about the fortification of cereal grain products, and you are talking about putting that level of nutrient in each one of those products or that level of nutrient in additional foods that may be designed specifically for the elderly, I think that is where you may get into a problem.

If you were just talking about fortification of bread, and there was no other problem, then there would probably be a very small segment of the population and they would have to consume a fairly large amount of it.

But let's face it. Whenever you are fortifying a very large variety of cereal grain products other than bread and you are also fortifying other foods—and you can use ready-to-eat breakfast cereals as a very good example, some of which contain the 100 percent level of the RDA for all of those nutrients for which we have an RDA—then I think that is where you possibly can get into a problem.

We all know that the American population, or at least most of the American population, does have a very significant feeling that if a little bit does a good job, then a lot does even better, and we can get, of course, problems in overfortification.

Also, approximately 50 percent of your population over 18 does seem to take, at least in part, a nutrient supplement which would be, of course, a vitamin pill. Now, that may not in fact have iron or minerals associated with it, but many of our nutrient supplements now do, including zinc, et cetera.

Mr. SHACKNAI. The chairman posed a question regarding vitamin supplementation to Dr. Miller when he testified, and, specifically, he asked what the data were based on for your statistic, 50 percent over the age of 18 and particularly of these special population groups that seem to be most nutritionally at risk, the poor and the elderly. What percentage of those groups are taking vitamin supplementation in oral form?

Dr. KIRK. I am talking about 50 percent of the population over 18, and I think you would have to be able to take a look at the nutritional survey data to come out exactly with what percentage of each of those populations.

I will indicate that we have done nutritional status and nutritional assessment studies in different population subgroups within Florida, and we have looked at the elderly, both on a race and ethnic basis as well as the juvenile—that would be the adolescent and the pregnant teenager—and we have found that yes, there are some nutrients, but it does not necessarily follow status line, and it does not necessarily mean that the poor are malnourished and that the wealthy or the upper middle class are well nourished. It crosses all types of boundaries, and many of the poor in fact are very well nourished.

Mr. SCHEUER. And I suppose many of the rich who have improper dietary habits could be inadequately nourished.

Dr. KIRK. That is very true.

Proceeding, then——

Mr. SHACKNAI. Excuse me. But doesn't the national data that we have heard so much about, ranging from the dietary consumption surveys to the HANES I data, indicate that the poor and the elderly are most nutritionally at risk for those nutrients that we are studying?

Dr. KIRK. Well, I think you have two areas that seem to be at-risk populations, and that is the adolescents and the young population, which are at a very rapid growth phase, and then, of course, the elderly.

Again, I hate to say that it is all due to dietary intake because we all know that there is a process that goes on called aging, and whether the aging process is a cross-linking process that affects nutrient uptake by cells in terms of being able to offer good biochemical reactions to occur in the body, or whether or not it is a situation where you have gene destruction and inability to synthesize certain compounds.

So there in fact lies a problem. I cannot tell you whether that is a problem in terms of biological availability or whether it is biological activity or whether it is lack of nutrient intake, all of which are problems.

Mr. SHACKNAI. But the gross nutrient intake, not adjusting for gene decomposition or any other biological factor, I think, would be indicated from the data to be lowest among those two special population groups. Would you not agree with that?

Dr. KIRK. Well, if you are talking about gross nutrient intake, if you are saying calories are lower in terms of calorie consumption in the elderly, that is true, they are lower, but I would also point out that there are a number of food products there which would offer the possibility of supplementation, and that, of course, is superfortified foods, as you might want to call them. That would be a fortified cereal product which contains 100 percent of the RDA, and that is a very economical way of fortification or enriching a person's diet or fortifying an individual's diet.

Yet we still seem to have some of these problems with us with certain nutrients.

I think, in concluding, I would really like to offer the recommendations that, No. 1, Congress insure that food fortification policy or policies be developed and implemented only when sufficient scientific evidence, including clinical data, is available.

Mr. SCHEUER. Do you think there is sufficient data now to indicate that the fortification standards should be raised?

Dr. KIRK. I would like to see what the HANES II survey data tell us. I think that is very important.

Mr. SCHEUER. Yes. Assuming that analysis of the HANES II data indicates that there is a nutritional problem, that those standards should be raised, would you feel comfortable seeing the FDA go ahead to pursue those?

Dr. KIRK. I think the FDA will feel comfortable themselves. Yes, I would feel comfortable that we move ahead.

Mr. SCHEUER. Yes.

Dr. KIRK. But again, I don't think we can do that without the basis of good data and good clinical data, as I said. That leads to the second, really, recommendation, that support be directed to the interpretation of the HANES II data in a reasonable time period and for generating additional data which will supplement data generated by HANES II.

As I indicated, we may not in fact be able to find out all the answers to the nutrients that were of question. We all know and have heard earlier from testimony that folate, B6, zinc, iron all present unique problems.

Three, support should be directed toward an ongoing surveillance program to monitor the effectiveness of the fortification program and to track changes in food technology and dietary patterns which would alter the effectiveness of a fortification program.

Four, that research relating nutrition to health, which includes the interface of nutrition and food science and technology, be supported at a level which would provide the necessary information to permit a rational and scientifically based fortification policy.

Five, that fortification should not be considered as a replacement for programs which permit selection of foods and development of good eating habits and social interaction which we know affect the physical, mental, and social health of any population.

Mr. Chairman, this ends my formal testimony. You have a copy of it in total.

[Material follows:]

Mr. **Scheuer.** Well, you have been very provocative, and you have given us very interesting testimony.

Mr. **Shacknai.** With respect, Dr. Kirk, to your reference to a false sense of security which might occur as a result of fortification of cereal grains, is it not the intellectual premise of fortification of cereal grains that there is a need for some sort of an insurance mechanism to make sure that the American public does in fact get at least minimal levels of recommended daily allowances? It is sort of based on the presumption that, left to their own devices, either for economic or educational reasons, the American public has not thus far been able to insure complete nutritional adequacy.

So, given all that, does the fortification of bread, which in the final analysis would probably be unknown to large segments of the American public, really present that risk of a false sense of security whereby a person would consume an entire loaf of bread and neglect other important food groups?

Dr. **Kirk.** Well, first of all, it is a very long question, so I am not sure that I will be able to answer it in a very short period of time.

Let me point out that what you are talking about is just fortifying bread, but that is not the only product that is being fortified, and I think you have to realize that and face that issue, that there are many other products that are fortified. Ready-to-eat cereals are fortified, formulated foods. Fabricated foods are all formulated. Bread is just one part of that total dietary picture, and you cannot look at bread and say that you want to put 100 percent of the nutrients in there because then you also have 100 percent in ready-to-eat cereals, certain ones; you have other problems. I think that is one problem in terms of overfortification.

The false sense of security comes from the fact that you are not dealing with a group of individuals who has a nutritional data base that many of us do or even a lot of us do in this room, and the problem then becomes that you are looking at 19 nutrients, or approximately 19, that have RDA's associated with those, and you can only fortify with those that have RDA's. What do you do with the other nutrients, the micronutrients, the trace elements? Do you give that person a false sense of security by saying to him or to her, Listen, this is a fortified product, an enriched product, and they again get the feeling that that is all they really need.

Mr. **Shacknai.** Do you really believe that the average consumer goes through that degree of analysis when purchasing a product and formulating their menu for a given week?

Dr. **Kirk.** Do I think they go through a false sense of security?

Mr. **Shacknai.** No, do you think that the average American consumer performs the type of analysis on RDA's——

Dr. **Kirk.** Oh, absolutely not, but on the other hand, the consumer doesn't necessarily know that they need the other subset of nutrients that are not present in the 19 that are fortified or enriched into that product.

Mr. **Shacknai.** But if you are conceding that this sort of analysis is not taking place, I don't see how the consumer could be lulled into this false sense of security, that somehow the bread or other cereal grain product, eaten alone to the neglect of other important food components, is going to give them nutritional adequacy.

Dr. **Kirk**. Well, I am not necessarily——

Mr. **Shacknai**. There is a missing link in the train of thought.

Dr. **Kirk**. Well, I think you are giving the consumer the idea or the benefit of knowing that the food is fortified. I don't think you are giving them a false sense of security. They look at what is on that package——

Mr. **Shacknai**. To the contrary.

Dr. **Kirk**. And if it says "fortified" or if it says "enriched," they feel it is enriched with nutrients. They don't necessary go down the list and say that, OK, it only has thiamine, riboflavin, et cetera, and I need all the rest of them; they take it as an enriched or fortified product and could be, particularly with the population subgroup that you are talking about, lulled into believing that they are well nourished.

Mr. **Shacknai**. But if the standards of identity are changed to reflect the higher nutrient levels, there is not going to be a distinction in the marketplace between those items that are fortified to this higher degree and those that are not, and therefore——

Dr. **Kirk**. You seem to be missing the point. The point is that you are only going to be able to fortify with those nutrients for which you have an RDA, and there are many other nutritional requirements that you are not going to be able to put in that loaf of bread.

Mr. **Shacknai**. Well, but how does that differ from the present reality? I mean, I think that that is an obvious point, but I still miss the causal link as to how a change in the standards of identity is going to somehow lead consumers to believe that just by eating certain food groups, they are going to have their adequate level of nutritional intake for that day.

I am not assuming, incidentally, in that analysis that the consumer does much of an evaluation at all of the types of food that they are going to consume. I assume to the contrary.

Dr. **Kirk**. That is right. They read the package and read key words on the package: "fortified," "enriched."

Mr. **Shacknai**. But are those key words there as a legal matter if the standards of identity are changed?

Dr. **Kirk**. You have a standard of identity on a product there called bread, and it still says "enriched bread" on that.

Mr. **Shacknai**. But current bread products say "enriched bread," too.

Dr. **Kirk**. That is right, so people are going to buy enriched bread, or they are going to buy——

Mr. **Shacknai**. But that is what they are buying now.

Dr. **Kirk**. That is right.

Mr. **Shacknai**. They are buying enriched bread now, but if you are raising the standards of identity to comport with higher nutritional levels, everything assumes that standard of identity. What is now enriched bread, what is Wonder Bread, what is Interstate Bread, continues to be the same only at higher nutritional levels.

Dr. **Kirk**. I am not disagreeing with that statement.

Mr. **Shacknai**. So where is the false sense of security that——

Dr. Kirk. The false sense of security is the fact that that individual, by eating fortified foods, feels that he is well nourished.

Mr. Shacknai. But they are eating fortified foods now, only at a lower level, foods that say "fortified," that say "enriched," but not at the levels that the National Academy of Sciences and other groups have recommended.

Dr. Kirk. Oh, no, that is not necessarily true, and you are also throwing all of this into a loaf of bread when in fact you don't make your entire dietary intake from a loaf of bread, nor do you necessarily do it on a 24-hour period. You have body pools of nutrients, and you are looking at what is the entire dietary plan, what is your entire dietary intake.

Mr. Shacknai. Right. We can continue this in writing, which would probably be fairer to the Congressman.

Dr. Kirk. I was asked questions. I guess I would like to ask the chairman a question if I could. It is rather unusual.

Mr. Scheuer. Well, ordinarily we are here to ask the questions and you are here to answer them, but let's reverse it. We will do a little role reversal.

Dr. Kirk. I noticed that in your press release for this subcommittee hearing on grain fortification that there was a statement that some experts have reported that these deficiencies, which I presume means nutrient deficiencies, have led to serious illnesses among the aged and the poor, particularly. I was wondering what scientific information or what published literature might have been used to state that.

Mr. Shacknai. Well, I think, without getting into a highly technical discussion, there are a number of publications from the National Institute on Aging, publications that have been considered and reformulated by the House Select Committee on Aging, which are the intellectual underpinnings of that statement. But I don't really know that there is great merit in discussing the content of a press release rather than the substance of a hearing which has been before you today.

Mr. Scheuer. All right. Minority counsel has a question.

Ms. Bach. I have one question, and this I would pose to any of our witnesses today, but because you are here, I will ask you, Dr. Kirk.

There is always one curious question that I have when we talk about fortifying foods and fortifying cereal products, and that is: Why has no one gone back and looked at the process with which we put our grains through, more specifically the question of unbleached flour versus bleached flour? Isn't it true that we take out most of the nutrients of the grain, and then in another process we put much of it back and call this enriching it?

It seems to me that we are creating more work and increasing the cost, and now there is an industry that has developed around this. In fact, we are not helping the consumer by taking nutrients out and then adding them back after bleaching. Isn't this term "enriched" a false inference?

Dr. Kirk. Well, first of all, to just correct a term or two in terms of not necessarily is enriched flour or flour used in terms of breadmaking bleached. Normally, I think bleaching, and I think the people from the American Cereal Association could respond to that better, but cake flour in terms of baking cakes may be bleached, but normal enriched flour, I think, for breadmaking is probably not bleached, although it is aged.

The question is, yes, you are milling or you are taking that flour and you are extracting it, whether it is a 90-percent extraction, an 80-percent extraction, or a 70-percent extracted flour. With each extraction, you are removing some nutrients from it. It comes down to the consumer preference.

If the consumer in the marketplace chooses to buy nonwhite bread or bread of less extraction, 80 or 90 percent, then I think it would be reflected in the marketplace, and then we would not in fact be selling white enriched bread and we would be selling more of the natural breads. So if the consumer wants to do that, I mean I think they relate that back to the marketplace.

Mr. Scheuer. It may be that the consumer wants white bread, but I know of no evidence that consumers want white bread with all the nutrients bleached out of them. Why do we permit the bread manufacturers to leach or bleach or whatever the term is——

Dr. Kirk. Well, I don't think they are either leached or bleached, but they are removed by milling.

Mr. Scheuer. Blanched.

Dr. Kirk. They are removed by the milling operation because a certain portion of the grain molecule is removed which contains higher levels of those particular nutrients.

Mr. Scheuer. Why do we permit them to do that?

Dr. Kirk. Well, I think this is something that has come down through the overall evolution of processing flour and in terms of getting white bread, and the consumer likes white bread.

Mr. Scheuer. Does the technology permit us to process flour and get white bread without blanching the nutrients out of it?

Dr. Kirk. I think you need to direct that question to the American Cereal Chemists Association.

Mr. Scheuer. Yes. I wish I had thought of it then. Go ahead.

Ms. Bach. That was my question. It just seemed always curious to me that we are taking some of the essential nutrients out and then we say we are adding them back in. It seems to be creating an expense.

Dr. Kirk. Well, it is, but I think you also have to get back to the point that you don't necessarily have to have each dietary component supplying all of those nutrients. It all goes into a total nutrient pool. Because you take some of those out, although you may fortify them back in, if you like white bread, you eat it, and it becomes part of your diet, and if you don't like bread that is not white, then you may not even eat bread, and therefore you would be reducing your total carbohydrate intake even more, or substituting it with something else.

Mr. Scheuer. All right. We have kept you here a long time and you have been very patient. We have benefited from your testimony, and we thank you very, very much.

Dr. Kirk. Thank you.

Mr. Scheuer. This hearing is hereby adjourned.

[Whereupon, at 4:21 p.m., the subcommittee recessed, to reconvene at the call of the Chair.]

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